Supreme Court, U. S.
FILED
JUL 28 1980
MICHAEL RODAK, JR., CLERK

NO. 80-259

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1980

GLEN L. RUTHERFORD, et al.,

Petitioners,

vs.

UNITED STATES OF AMERICA, et al.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

KIRKPATRICK W. DILLING
DENNIS M. GRONEK
ROBERT E. ARMSTRONG
188 W. Randolph St.
Chicago, Ill. 60601
(312) 236-8417

KENNETH RAY COE
101 Park Avenue
Oklahoma City,
Oklahoma 73102
(405) 235-8593

Attorneys for Petitioners

NO.

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1980

GLEN L. RUTHERFORD, et al.,

Petitioners,

vs.

UNITED STATES OF AMERICA, et al.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

KIRKPATRICK W. DILLING
DENNIS M. GRONEK
ROBERT E. ARMSTRONG
188 W. Randolph St.
Chicago, Ill. 60601
(312) 236-8417

KENNETH RAY COE
101 Park Avenue
Oklahoma City,
Oklahoma 73102
(405) 235-8593

Attorneys for Petitioners

QUESTIONS PRESENTED

1. Whether Laetrile is exempt from the premarketing clearance requirements of the Federal Food, Drug, and Cosmetic Act by operation of the Act's 1962 grandfather clause.

2. Does denying cancer patients the right to use a nontoxic substance in connection with their personal health infringe constitutionally protected privacy interests?

PARTIES

GLEN L. RUTHERFORD, Individually and on behalf of a class composed of terminally ill cancer patients,

Petitioners,

vs.

UNITED STATES OF AMERICA, Joseph A. Califano, Secretary of Health, Education and Welfare, Donald Kennedy, Commissioner of the Food and Drug Administration, et al.,

Respondents.

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	2
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED	3
STATEMENT OF CASE	6
REASONS FOR GRANTING WRIT	10
Introduction	10
Cancer, the Underlying Problem.	12
Laetrile Is Exempt from the Premarketing Clearance Requirements of the Federal Food, Drug, and Cosmetic Act by Operation of the Act's 1962 Grandfather Clause	17
Laetrile "Generally Recognized as Safe"	23
The FDA "Double Standard of Safety"	24
Denying Cancer Patients the Right to Use a Nontoxic Substance in Connection with their Personal Health Infringes Constitutionally Protected Privacy Interests	28

Page

CONCLUSION..... 42

APPENDIX..... A-1

TABLE OF AUTHORITIES

Cases

	Page
Application of President and Directors of Georgetown College, 331 F.2d 1010 (D.C. App. 1964)	31
Doe v. Bolton, 410 U.S.,1979 (1973)	33,35
Eisenstadt v. Baird, 465 U.S. 438 (1972)	33
Erickson v. Dilgard, 252 N.Y.S. 2d 705 (1962)	32
Griswold v. Connecticut, 381 U.S. 471 (1965)	30,33
In Matter of Quinlan, 355 A.2d 647, cert. den.,429 U.S. 922 (1976)	39
Jacobson v. Massachusetts, 197 U.S. 11 (1904)	32, 37,40
Kent v. Dulles, 357 U.S. 116(1958)	36
Olmstead v. United States, 277 U.S. 438 (1928)	30
Roe v. Wade, 410 U.S. 113 (1973)	30,33, 34,38, 39
Rutherford v. U. S., 542 F.2d 1137 (10th Cir. 1976)	21,22
Schloendorff v. Society of New York Hospital, 211 N.Y. 125 (105 N.E. 92)	31

Whalen v. Roe, 429 U.S. 589,
51 L. Ed. 2d 64..... 37,38

Other Authorities

Merck Index (1907 Ed. 1940 Ed. and
Current - 9th Ed.)..... 18

Physicians' Desk Reference, 33rd
Ed., 1979..... 26

5 U.S.C.A., Sec. 554(c)..... 22
5 U.S.C.A., Sec. 556(d)..... 22

Section 201(p) of the Federal Food,
Drug, and Cosmetic Act..... 23

42 Fed. Reg. 10066 (1977)..... 19

42 Fed. Reg., No. 151, Page 39768..... 18

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1980

GLEN L. RUTHERFORD, et al.,

Petitioners,

vs.

UNITED STATES OF AMERICA, et al.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

To the Honorable, the Chief Justice and Associate Justice of the Supreme Court of the United States:

GLEN L. RUTHERFORD, et al., the petitioners herein, pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Tenth Circuit entered in the above-entitled case on February 19, 1980.

OPINIONS BELOW

After the United States Court of

Appeals for the Tenth Circuit remanded the case to the Food and Drug Administration (542 F. 2d 1137), the District Court, Honorable Luther L. Bohanon, District Judge presiding (at 438 F. Supp. 1287), ruled in favor of petitioners and the U. S. Court of Appeals for the Tenth Circuit (at 582 F. 2d 1234), affirmed in part.

On grant of certiorari, this Court (at 442 U. S. 544, 99 S. Ct. 2470, 61 L. Ed. 2d 68) reversed and remanded for the 10th Circuit U. S. Court of Appeals to rule upon the issues as determined by the District Court.

The opinion of the United States Court of Appeals for the Tenth Circuit, on remand, reversing and remanding the decision of the District Court, is reported at 616 F. 2d 455 and is included in the Appendix hereto, infra, page A-1.

JURISDICTION

The judgment of the United States Court of Appeals for the Tenth Circuit (Appendix, infra, page A-1) was entered on February 19, 1980. A timely petition for rehearing was denied on April 28, 1980. (Appendix, infra, page A-12) The jurisdiction of the Supreme Court is invoked under 28 U. S. C. 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Amendment I to the United States Constitution

2. Amendment IV to the United States Constitution

3. Amendment V to the United States Constitution

4. Amendment IX to the United States Constitution

5. Amendment XIV to the U. S. Constitution

6. 21 U.S.C.A., Section 321(g)(1):

> "The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories."

7. 21 U.S.C.A., Section 321(p), provides in pertinent part:

> "The term 'new drug' means --
>
> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof."

8. Section 107(c) of the Drug Amendments

of 1962, Pub. L. No. 87-781 (76 Stat.789)

(1962 grandfather clause) provides:

> "In the case of any drug which, on the day immediately preceding the enactment date (October 10, 1962) (A) was commercially used or sold in the United States, (B) was not a new drug as defined by Section 201(P) of the Basic Act as then in force (21 U.S.C.A. 321(p)) and (C) was not covered by an effective (new drug) application under Section 505 of that (Act 21 U.S.C. 355), the amendments to Section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug on that day."

9. 5 U.S.C.A., Section 706, Scope of Review:

> "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall --
>
> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be --
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right,

power, privilege or immunity;

(C) In excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) Without observance of procedure required by law;

(E) Unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) Unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing Court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error."

STATEMENT OF CASE

By way of background, in 1975, terminally ill cancer patients and their spouses brought this action to enjoin the Government from interfering with the interstate shipment and sale of Laetrile, a drug widely used by cancer patients and their Doctors.

Finding that Laetrile, in proper dosage, was non-toxic and effective, the District Court ordered the Government to permit

limited purchases of the drug by one of the named plaintiffs. 399 F. Supp. 1205, 1215 (WD Okla. 1975). On appeal by the Government, the 10th Circuit U. S. Court of Appeals did not disturb the injunction. However, it instructed the District Court to remand the case to the Food and Drug Administration for determination whether Laetrile was a "new drug" under Sect. 201(p)(1),and if so, whether it was exempt from premarketing approval under either of the Act's grandfather clauses. 542 F.2d 1137 (1976).

After completion of administrative hearings, the Commissioner issued his opinion on July 29, 1977; 42 Fed. Reg. 39768 (1977), that Laetrile was a "new drug" requiring premarket approval, it not being exempted because "generally recognized as safe and effective", or exempted under the 1938 and 1962 "grandfather clauses" of the Federal Food, Drug and Cosmetic Act.

On review of the Commissioner's decision, the District Court, concluding that the record did not support the Commissioner's findings as to the 1962 grandfather provision, ruled that Laetrile was entitled to an exemption from premarketing approval requirements. 438 F. Supp. at 1294-1298. Alternatively, the Court held that, by denying cancer patients the rights to use a nontoxic substance in connection with their personal health, the Commissioner had infringed constitutionally protected privacy interests. Id., at 1298-1300.

Meanwhile, by order entered April 8, 1977, the District Court certified a class consisting of terminally ill cancer patients. 429 F. Supp. 506 (WD) Okla. 1977). The Government did not seek review of that order. The District Court had also entered orders for individuals who submitted affidavits averring their membership in the certified

class of cancer patients. This "affidavit system" is currently in effect, making possible availability of Laetrile to U. S. cancer patients and their physicians, whether or not they reside in one of the 22 states which have specifically enacted Laetrile enabling laws, or elsewhere.[1]

Following the District Court rulings, and further proceedings in the 10th Circuit U.S. Court of Appeals and this Court, the cause was remanded to the U. S. Court of Appeals for review of the District Court's rulings on the constitutional and grandfather clause questions. (United States v. Rutherford, 442 U.S. 544, at 559 note 18,

---

1. Alaska (See Alaska Statutes 08.64.367); Arizona (See A.R.A. 36-2451); Delaware (See Del. Code Ann. 16 Section 4901); Florida (See F.S.A. 458.24); Idaho (See Idaho Code 18-7301A); Illinois (See S.H.A. 56½, Section 1801); Indiana (See Burns Ind. St. Ann. 16-8-8-1); Kansas (See S.B. 505 May 8,1978); Louisiana (See L.S.A. -- R.S. 40:676); Maryland (See Ann. Code of MD, Art 43 Sec.

(June 18, 1979).

On February 19, 1980, the Court of Appeals reversed the District Court, ruling against petitioners on the Constitutional and Grandfather clause questions.

Petitioners timely filed their petition for rehearing, which was denied on April 28, 1980.

REASONS FOR GRANTING WRIT

Introduction

This cause involves fundamental Constitutional issues of transcendant importance that affect an entire class of persons, namely terminally ill and other cancer

---

1 (continued)

133 ch 809); Nevada (See Nev. Rev. St. 630.303); New Hampshire (See R.S.A. 329;30); New Jersey (See N.J.S.A. 24:6F-1); North Dakota (See H.B. 1214 eff. July 1, 1979); Oklahoma (See 63 Okl. St. Ann. Sec. 2-313); Oregon (See Oregon Rev. St. 689.885); South Dakota (Bill Number 1287 signed 3/16/79 eff. 7/1/79); Texas (See Vernon's Ann. Civ. St. 71 art.4476-5a); Washington (See R.C.W.A. 70.54.130); Montana and Colorado have also enacted Laetrile legislation, and, in 1980,

patients, the number of cancer patients currently receiving Laetrile, or Amygdalin, pursuant to the legalities heretofore rendered in this cause, comprising 75,000 or more persons. If the FDA is successful herein, as it has been thus far, no one, not even a terminal cancer patient, may receive Laetrile in any form, and thousands of patients now dependent upon Laetrile will be effectively left to die without the treatment they now value for their very lives.

Petitioners respectfully submit that grave and important issues of Due Process and Constitutional Rights to Privacy are present in the above cause, and that it is

---

1 continued

Kentucky. Certain state laws, such as enacted in Illinois, include provisions for "informed consent" to be rendered by the treating physician, and acknowledged by the cancer patient, before treatment with Laetrile commences. In the main these statutes properly equate "Laetrile" and "Amygdalin". All of these State laws were enacted only after

appropriate that this Court consider, on writ of certiorari, all of the issues involved.

Petitioners therefore pray that this Court's discretion be exercised in this case and that a writ of certiorari issue to review the judgment of the United State Court of Appeals for the Tenth Circuit (appendix, infra, page A-1), if only because said Court of Appeals has decided important questions of Constitutional and Federal law which have not been, but should be, settled by this Court.

Cancer -- The Underlying Problem

In 1977, 400,000 Americans died of cancer, a figure which is seven times the total fatalities in the Vietman and Korean Wars.

1 continued

extensive hearings, research, and debate. Laetrile legislation is presently pending in various other States. Rather obviously, banning Laetrile for interstate shipment to a cancer patient would nullify all of the

According to Dr. Marvin Schneiderman, Associate Director of the National Cancer Institute, a government agency which receives approximately $800,000,000.00 per year in taxpayers' funds, the death rate from all types of cancer is continuing to increase. Dr. Schneiderman also states that cancer mortality, overall, is increasing, so that it is the only major cause of death which has continued to rise from 1900 through 1976. Putting it another way, more people are dying from cancer in every age group than have died from cancer in such age groups at any other time in American history. According to present projections, 1 in 4 Americans is doomed to die of cancer. Pursuant to the best available Government

---

1 continued

existing State Laetrile laws, and State sanction of Laetrile use where such legislation has not yet been enacted.

statistics, the cancer death rate in 1900 was 64 per 100,000 of the population, a figure which has now increased to 162.8 per 100,000, or almost a three-fold increase. As recently as 1965, the cancer death rate per 100,000 persons was only 127.9. Within the overall statistics, there are equally unfavorable figures as to specific types of cancer. For example, between 1973 and 1975, the number of lung cancer cases increased in the United States 13%, breast cancer, 17%, stomach cancer, 28%, and prostate cancer, 32%, for the same period. Nor is median survival time particularly encouraging for the cancer sufferer. According to the U. S. Department of Health, Education, and Welfare, the observed median survival time in approximately 219,500 cases of cancer (all sites) was 1.7 years. This median survival time includes those cases wherein a cancer is localized, or limited to the site or origin. Of great interest to the

matter at bar, however, are the statistics concerning distant (disseminated or "metastasized") cancer, wherein the U. S. Government has stated that the five-year relative survival rate ranges from a maximum of 17% for prostate cancer, to 14% for corpus uteria cancer, 12% for cervix cancer, 10% for female breast cancer, 8% for ovary cancer, 5% for colon cancer, 2% for stomach cancer, 1% for lung and bronchur cancer, and a "zero" survival rate for pancreas cancer for that period. The overall death rate for those afflicted by distant or disseminate cancers, after a period of five years, is 91%.[2]

Petitioners consider this latter figure to be of particular significance herein, due to

---

2. See testimony of Dr. Marvin Schneiderman, Associate Director, National Cancer Institute, March 5, 1979, before Special Subcommittee, U. S. Senate, Edward Kennedy, Chairman;"Facts of Life and Death", U. S. Department of Health, Education, and Welfare Publication No. (HRA) 74-1222; "Mortality Trends for Leading Causes of Death", U. S. Department of Health,

the fact that the plaintiffs, together with thousands of other patients who have availed themselves of Laetrile or amygdalin are "terminal", namely, no conventional therapy is of any avail to prolong their lives beyond the dismal life span heretofore shown by the government's statistics, and which inescapably reflect the inadequacy and inefficacy of conventional cancer therapies. Thus, Petitioner Rutherford and those others who have petitioned the Courts, and who also have been recognized by the legislatures of 22 states to date, believe that Laetrile offers hope as against virtually no hope whatsoever from conventional therapies.

Basic to the arguments heretofore presented to this Court by FDA is the "rosy", but totally

---

2 Continued

Education, and Welfare Publication No. (HRA) 74-1853; "Ca-Cancer Journal for Clinicians"; "Cancer Rates and Risks", 2nd Edition, U. S. Department of Health, Education, and Welfare Publication No. NIH 75-691.

unjustified "imputation" that with orthodox, or conventional, cancer therapies we are rapidly winning the battle against cancer,and that, therefore, we need look no further to such therapies as those afforded by Laetrile, and its accompanying metabolic therapies as employed by physicians throughout the United States, and over the World. However, as noted hereinbefore, the Government's own statements and statistics demonstrate that we are not winning the battle against cancer, but losing it very rapidly, the conventional therapies being totally inadequate to handle the problem.

Laetrile Is Exempt from the Premarketing Clearance Requirements of the Federal Food, Drug, and Cosmetic Act by Operation of the Act's 1962 Grandfather Clause

This Court's previous decision did not rule upon this issue, merely remanding this cause to the U. S. Court of Appeals for such ruling.

The District Court found that in every respect, Laetrile met the criteria of the "1962 Grandfather Clause" to the Federal Food,

Drug, and Cosmetic Act, its opinion detailing at length the underlying and substantiating reasons therefor.

Certiorari should be granted herein if only because the Appeals Court's recent opinion herein misconstrues the factual circumstances and also the factors involved as to the "grandfathering" of Laetrile, or amygdalin, pursuant to the 1962 statute in question. For example, the Appeals Court's opinion stated "there has not been the consistency in the formula which the FDA requires under its current practice."

This is entirely contrary to fact, even as noted in the"Commissioner's Decision on Status" (42 Federal Register, No. 151, Page 39768, et seq.), wherein the FDA Commissioner noted that the Merck Index, 9th Edition, designates "laetrile" as "a term used interchangeably with 'Laetrile', 'amygdalin', nitriloside', and 'vitamin B-17'." The record also clearly shows that the chemical composition of

"amygdalin", or "Laetrile", is now new, but has been known to science since at least 1845.

The Commissioner himself recognized the simple identity of the substance which was the subject of his rule-making proceeding when the first notice of rule making was published, 42 Fed. Reg. 10066 (1977):

> "Laetrile is the name of a product whose major component or ingredient is Amygdalin, a substance that occurs naturally in the pits of apricots, peaches, bitter almonds and in other plant material ... and its has been known, tested and used (as a cancer remedy) for more than twenty-five years ..."

Similar references to the factual circumstances which support all of the criteria necessary to constitute Laetrile, or amygdalin, as being "grandfathered" can be cited. These are covered in great detail by the District Court's rulings below. (See 435 F. Supp. 1287).

In this regard, however, perhaps the most serious and substantial misconstrual of the matters relating to whether or not Laetrile is

"grandfathered" relate to the AppealsCourt's rulings concerning the administrative record before the U. S. Food and Drug Administration. In effect, the Court's recent opinion reverses the "burden of proof" which was incumbent upon FDA, placing it upon petitioners, and also, in substance, attributing the blame for alleged inadequacies in the administrative record upon petitioners, as well.

FDA opposition to Laetrile has been implacable, even as the within cause was commenced in 1975, when petitioner Rutherford's Laetrile having been seized by FDA, he sought Court intervention. At that time, FDA had conducted no administrative proceedings whatsoever to determine the legal status of Laetrile. On October 12, 1976, the Appeals Court upheld the District Court, its opinion stating that Laetrile "is not a new drug merely because they" (i.e., FDA) "say it is." The Court then ordered an administrative review by FDA, which in turn led to the rulemaking proceeding mentioned in the Appeals Court's most recent opinion.

By the order of the Appeals Court upon its remand of this case to the Food and Drug Administration, (Rutherford v. United States, 542 F. 2d 1137 (10th Cir. 1976)), it was stated:

> "To support its determination, the FDA in the case at bar would have to present substantial evidence to support the proposition that Laetrile is not generally recognized among qualified experts as 'safe and effective' and that Laetrile is not grandfathered by either of the exemptions discussed above."

The administrative proceeding belied any openminded review by the Food and Drug Administration. In the matter at hand, the FDA Commissioner elected to conduct hearings under provisions for the most informal proceedings allowed. These informal proceedings inevitably resulted in a denial of the right to cross-examine witnesses, also allowing testimony to be given without requiring an oath. Petitioners' attorneys objected to this procedure, but the Hearing Examiner proceeded nevertheless (Administrative Rule Making Hearing, Oral Argument, pp. 10, 11, 27 and 28).

Contrarily, the Appeals Court had mandated hearings which would guarantee cross-examination, pursuant to 5 U.S.C.A., Section 554(c). Rutherford v. U.S., 542 F. 2d 1137 (1976). The cited provision comprehends that hearings conducted thereunder must be pursuant to Sections 556 and 557 of the Administrative Procedure Act. Section 556 of the Act provides under sub-part (d):

> "... a party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts..."

However, FDA deliberately denied petitioners their proper administrative proceedings mandated by the Appeals Court, and generally carried out the proceedings in such a way as to guarantee that the FDA's already predetermined position on Laetrile would prevail.

Any "frailties", therefore, in the administrative record before FDA were, and are, the sole and only responsibility of the Agency itself, and should not have been cause to reverse

the findings of the District Court that indeed Laetrile is "grandfathered" pursuant to the appropriate provisions of the Federal Food, Drug, and Cosmetic Act. The record herein, nevertheless, amply reveals that FDA did not meet its burden of proof as mandated by the Court, nor did it conduct proper administrative proceedings, as also mandated by the Appeals Court.

Even then, to the maximum extent possible, and acting under the handicaps aforesaid, the record herein does reveal that all of the criteria of the 1962 Grandfather Clause were met. This Court should therefore grant certiorari, with the above in view.

Laetrile"Generally Recognized as Safe"

There is no question but that a drug meeting the criteria of the 1962 Grandfather Clause, as indeed Laetrile does, is an exempted substance if it also was, as of October 9, 1962, "generally recognized, among experts qualified to evaluate the safety of drugs, as safe for use..." (Section 201(p) of the Act as in effect

October 9, 1962).

The District Court, based upon ample support in the record, found that Laetrile "was generally recognized as safe" and otherwise met the criteria of the 1962 Grandfather Clause.

The Court's findings included:

> "Extensive use of the substance, its commercial availability, and its recognition as being safe, all previous to 1962, are well documented in the record."

And:

> "The administrative record brooks little real controversy as to Laetrile's non-toxicity, particularly when administered parenterally, even at doses greatly exceeding amounts normally ingested."

The District Court's findings regarding the "safety" and "generally recognized as safe" 1962 status of Laetrile were not rendered in a "vacuum", so to speak, but with ample substantiation in the record.

The FDA "Double Standard" of Safety

In an attempt to reverse these findings, respondents herein represented to this Court in previous proceedings that somehow Laetrile is "not safe", but "toxic" (in the oral form, at least), and that therefore Laetrile does not

meet the alleged "strict standards" of "safety" which are purportedly a prerequisite to Food and Drug Administration approval of any anti-cancer drugs.

Nevertheless, nowhere in the voluminous proceedings of this cause, has FDA indicated what such "safety" standards might be, to be applied by this Court.

Whatever the case, presumably FDA has applied standards of "safety" in numerous instances whereby anticancer drugs have been approved by the Agency for use by physicians, and for administration to cancer patients.

However, in fact very toxic, grossly dangerous, lethal and fatal "anticancer" drugs have been approved in the name of "safety" by the Agency, while FDA has not even-handedly and non-discriminatorily applied to Laetrile the same standards by which it measures other anticancer drugs for "safety".

Not one "anticancer" drug thus far approved by FDA for "safety" and "efficacy" is actually "safe", but such drugs are extremely toxic and

dangerous, even causing death, not to mention destroying the body's immune systems and actually causing cancer, among other things.[3]

---

3. Some of the "anticancer" drugs currently marketed with FDA approval include (information based upon FDA-approved labeling, and prepared by manufacturer, each instance, published in Physicians' Desk Reference, 33rd Edition, 1979): CYTOXAN (Mead Johnson & Co.), a drug which can cause death, and can also cause cancer; ADRIAMYCIN (Adria Laboratories, Inc), "Cardiac toxicity" is exhibited by this drug, and congestive heart failure and/or cardiomyopathy may be encountered. There is a "high incidence of bone marrow depression" and administration of the drug "may result in superinfection or hemorrhage"; ADRUCIL (Adria Laboratories, Inc.) A "highly toxic drug with a narrow margin of safety" and "severe hematologic toxicity, gastrointestinal hemorrhage, and even death may result" from use of the drug; BICNU (Bristol Laboratories, Division of Bristol Myers Co.) "Delayed bone marrow toxicity is the major toxicity", and the drug can cause cancer; DTIC (Dome Division, Miles Laboratories, Inc.) "Leukopenia and thrombocytopenia may be severe enough to cause death." ; MUTAMYCIN (Bristol Laboratories, Division of Bristol Myers Co.) "Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of Mutamycin." The drug can also cause cancer, with an increase of 50% to 100% in cancer tumors; MATULANE (Roche Laboratories) It can be cancer-causing

How, in the face of the "anticancer" drugs approved by FDA for their "safety" could anyone claim that Laetrile is not only totally "safe, but "generally recognized as safe", as well, either now or in 1962? Petitioners respectfully urge that a rule of common sense should be applied to the criteria as to Laetrile, and concerning which the same is

---

3. Continued

"Leukemia, among other things, has resulted from Matulane therapy"; MITHRACIN (Manufactured by Pfizer Laboratories for the Dome Division, Miles Laboratories, Inc.) "Severe thrombocytopenia, a hemorrhagic tendency and even death may result from the use of Mithracin."; FUDR (Hoffman LaRoche, Inc.) "Severe hemotological toxicity, gastro-intestinal hemorrhage and even death may result from the use of FUDR despite meticulous selection of patients and careful adjustment of dosage ..."; FLUORACIL (Hoffman LaRoche, Inc.) "Severe hemotological toxicity, gastrointestinal hemorrhage and even death may result from the use of Fluorouracil despite meticulous selection of patients and careful adjustment of dosage."; METHOTREXATE (Lederle Laboratories) "Sudden death has been reported from use of Methotrexate."; BLENOXANE (Bristol Laboratories, Division of Bristol Myers Co.) "Pulmonary fibrosis" (i.e.,progressive fibrous degeneration of the lung" is the most severe toxicity associated with Blenoxane."

totally "nontoxic", and "safe", if only judged by the standards heretofore applied by FDA itself as to approved drugs now available and employed by Doctors for their cancer patients.[4]

Denying Cancer Patients the Right to Use a Nontoxic Substance in Connection with their Personal Health Infringes Constitutionally Protected Privacy Interests

Contrary to the detailed and exhaustive findings and opinion of the District Court, the Appeals Court's recent opinion finds that petitioners have no constitutional right of privacy as to use of Laetrile. In so finding, it is respectfully submitted that such Court applied the wrong standard in evaluating whether or not petitioners do indeed have a constitutional right of privacy in this area.

4. Petitioners note a recent report (United Press International, June 28, 1980) that Laetrile, administered to human cancer patients at the Mayo Clinic, under National Cancer Institute auspices, has passed safety tests.

In particular, the Appeals Court's recent opinion disclaims any "useful purpose" to review a number of this Court's decisions regarding constitutional rights of privacy in various health areas, concluding that petitioners herein would have no right of privacy as to Laetrile inasmuch as the denial thereof is "within the area of governmental interest".

However, the Constitutional standard to be properly applied in this regard is not as stated by the lower Court, but whether or not there is a"compelling governmental interest" to deny Laetrile to terminal and other cancer patients. In this regard, petitioners cite the numerous citations of this Court, hereinafter mentioned in part.

It is also submitted that the lower Court's recent opinion fails to take into account an equally important "area of governmental interest" inherent in the fact that twenty-two States have thus far enacted legislation specifically permitting and approving the use

of Laetrile for their citizens, and wherein there is actually recognition, therefore, of a "compelling governmental interest" in making available Laetrile to cancer patients in those states.

The Right of Privacy was first enunciated by this Court in Griswold v. Connecticut, 381 U.S. 471 (1965). The right has been found to emanate from the penumbras of the 1st, 4th, 5th, 9th and 14th Amendments to the Constitution. Roe v. Wade, 410 U. S. 113 (1973). The Privacy Right has been recognized as "fundamental". Griswold v. Connecticut, supra.

The language of Mr. Justice Brandeis in his dissenting opinion in Olmstead v. United States, 277 U. S. 438, 478 (1928), remains vital today:

> "The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans and their beliefs, their

their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone -- the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation..."

Judge Cardozo (and later Justice of this Court) in Schloendorff v. Society of New York Hospital, 211 N.Y. 125 (105 N.E. 92, page 93) stated:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body;..."

The right to control one's own body is not restricted to the wise; it includes the "foolish"refusal of medical treatment. Nor is this right limited in its recognition to any single segment of the political, economic, or social thought spectrum.

In Application of President and Directors of Georgetown College, 331 F. 2d 1010, 1017 (D.C. App. 1964), Judge (now Chief Justice of this Court) Burger, in his now well-known dissent, commented upon the applicability of

Mr. Justice Brandeis' concept of the Right of Privacy:

> "Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights only as to sensible beliefs, valid thoughts, reasonable emotions, or well-founded sensations. I suggest that he intended to include a great many foolish, unreasonable, and even absurd ideas which do not conform, such as refusing medical treatment, even at great risk."

The right to refuse any and all medical treatment has been recognized by the Supreme Court. Jacobsen v. Massachusetts, 197 U.S. 11 (1904). This same principle has been affirmed even despite risk of death. Erickson v. Dilgard, 252 N.Y.S. 2d 705, 706 (1962). The Court in Erickson stated:

> "... it is the individual who is the subject of a medical decision who has the final say and that this must necessarily be so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires."

To recognize a right to decline medical attention of any kind, while denying a right of terminal cancer patients to utilize the

nontoxic substance Laetrile, would create a bizarre anomaly in the law.

The District Court's decision herein, allowing the use of Laetrile by terminally ill cancer patients, falls within the Right to Privacy previously enunciated by this Court.

This Court has dealt with the privacy right in several recent cases within a health context. Roe v. Wade, supra; Doe v. Bolton, 410 U.S. 179 (1973); Griswold v. Connecticut, supra; and Eisenstadt v. Baird, 465 U. S. 438 (1972).

In Griswold, it was held that a state could not ban the use of contraceptives without abridging a couple's right to privacy which underlies a marriage relationship. The Court recognized the Right of Privacy within the general spirit of health care.

Eisenstadt upheld the right of a person to distribute contraceptives on grounds that statutes prohibiting distribution to single people violated equal protection by distinguishing between the married and single people.

The Court stated at 453:

> "If the Right of Privacy means anything, it is the right of the individual, married or single, to be free from unwarranted government intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

In the landmark case, Roe v. Wade, supra, this Court expanded the Right of Privacy to encompass a woman's decision to have an abortion. The Court found that the right to an abortion was a "fundamental" right.

The decision in Roe, supra, was based, at least in part, on the health of the mother. Roe at 727:

> "The detriment that the State would impose upon the pregnant woman by denying this choice altogether is apparent. Specific and direct harm, medically diagnoseable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon a woman a distressful life in the future. Psychological harm may be eminent. Mental and physical health may be taxed by child care."

Certainly the psychological and physical well-being of the terminally ill cancer patients herein deserves as much protection by this Court as the "possible" harm to a woman

as a result of child care, caused by the lack of an abortion. Regardless of the weight given the health factor in Roe, the health of the pregnant woman is inextricably involved in the Court's rationale allowing abortions.

In declaring the statutes prohibiting abortion to be unconstitutional, the Court balanced that right against what was asserted by many as the "Right to Life" for the unborn fetus.

Even considering the asserted rights of the unborn fetus, this Court did not find them strong enough to deny the mother's right to privacy.

Doe v. Bolton, supra, another abortion case handed down by this Court on the same day as Roe, also struck down criminal abortion statutes as unconstitutional.

Mr. Justice Douglas, in his concurring opinion in Doe v. Bolton, 410 U.S. 179, 213 (1973), recognized the fundamental nature of the freedom to care for one's own health:

"Third is the freedom to care for one's health and person, freedom from bodily restraint or compulsion, freedom to walk, stroll,or loaf."

Mr. Justice Douglas commented further about the right to health care at page 219:

"The right to seek advice on one's health and the right to place reliance on the physician of one's choice are basic Fourteenth Amendment values. We deal with fundamental rights and liberties, which, as already noted, can be contained or controlled only by discretely drawn legislation that preserves the 'liberty" and regulates only phases of the problem of compelling legislative concern."

The privacy right includes the privilege of an individual to plan his own affairs, for "outside areas of plainly harmful conduct, every American is left to shape his own life as he thinks best, do what he pleases, go where he pleases." Kent v. Dulles. 357 U.S. 116.126 (1958).

Many of the cancer patients involved in this matter have heard the death sentence from their own doctors. They have been told that orthodox medicine holds no hope for them and that they are suffering from cancer in its

"terminal" state. They are perfectly free to decline treatment of any kind. Jacobson, supra. Yet, under the construction of the Food, Drug, and Cosmetic Act asserted by FDA, they may not seek hope from the nontoxic substance Laetrile.

Those patients with requisite wealth can avoid this bureaucratic ban by obtaining treatment in countries such as Mexico, where Laetrile is legal, even welcomed, but this alternative is not available to the poor or the bedridden.

The ban of Laetrile by the Food and Drug Administration has resulted in a severe limitation on cancer patients' exercise of free judgment in matters directly affecting the quality of their lives. It cannot be asserted that these terminal cancer patients are being granted their "right to be let alone" as long as they are denied free access to Laetrile.

In Whalen v. Roe, 429 U. S. 589, this Court considered the New York statutory requirements with respect to prescriptions for "dangerous,

legitimate" drugs. The requirement in question was that of notification. The Court balanced the invasion of the zone of privacy against the public's right involved and concluded that with respect to the particular type of drugs involved the statutes were a reasonable exercise of the state's broad police power. In so holding, the Court discussed the right of an individual to choice of treatment, saying:

> "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication ... Within dosage limits which appellees do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient." Whalen v. Roe, supra, 429 U.S. 589, 603 (51 L.Ed. 2d 64, 75-76, 97 S.Ct. 869, 878).

In the matter at hand, FDA would leave no such decision to either physician or patient.

Personal rights that may be deemed "fundamental" or "implicit" in the concept of ordered "liberty" are included in this guarantee of personal privacy (410 U.S. 113, 152, 35 L. Ed. 2d 147, 176). In his concurring opinion in the Roe case, Justice Douglas recognized that

the "freedom to care for one's health and person" comes within the purview of the right to privacy (410 U.S. 179, 213, 35 L.Ed. 2d 147, 188). Justice Douglas continued:

> "It is one thing for a patient to agree that her physician may consult with another physician about her case. It is quite a different matter for the State compulsorily to impose on that physician-patient relationship another layer or, as in this case, still a third layer of physicians. The right of privacy -- the right to care for one's health and person and to seek out a physician of one's own choice protected by the Fourteenth Amendment -- becomes only a matter of theory, not a reality when a multiple-physician-approval system is mandated by the State.
>
> * * *
>
> "The good-faith decision of the patient's chosen physician is overridden and the final decision passed on to others in whose selection the patient has no part. This is a total destruction of the right of privacy between physician and patient and the intimacy of relation which that entails." (Roe v. Wade, 410 U.S. 113, 219, 35 L.Ed. 2d 191,192).

In Matter of Quinlan, (355 A. 2d 647,cert. den., 429 U.S. 922, 1976), the Supreme Court of the State of New Jersey held in a declaratory judgment proceeding that the parent and guardian of an incompetent woman could assert

on her behalf her constitutional right to privacy. The Court further held that its decision need not be controlled by the consensus of opinion of physcians who were qualified experts, namely, that withdrawal of the support of a respirator would not conform to standard medical practices and would result in Karen Quinlan's death soon thereafter (355 A. 2d 647, 669). The decision on whether or not to remove the respirator properly rested with Karen's parents and attending physicians.

FDA has made no real argument that the use of Laetrile by terminal or other cancer patients would in any way, offend the rationale of Jacobson, supra, because there is no intrusion upon the "safety of the general public."

It is paradoxical that FDA appears more interested in a potential harm to their ostensibly rigid and inflexible "system" of control over drugs than in the human and other issues presented in this case.

Any "compelling state interest" protecting

its"system" asserted herein by FDA simply does not exist. Plaintiffs' constitutional rights of due process and privacy require that they and their doctors be granted access to Laetrile.

The issue is best framed in the language of the District Court (438 F. Supp. 1287) wherein Judge Bohanon noted:

> "As a nation, however, historically and continuously, we are irrevocably committed to the principle that the individual must be given maximum latitude in determining his own personal destiny.
>
> "To be insensitive to the very fundamental nature of the civil liberties at issue in this case, and the fact that making the choice, regardless of its correctness, is the sole prerogative of the person whose body is being ravaged, is to display slight understanding the essence of our free society and its constitutional underpinnings. This is notably true where, as here, there are no simple answers or obvious solutions, uncertainty is pervasive, and even the best efforts leave so much to be desired.
>
> "The final consequences are ultimately borne by those whose bodies are the battleground on which cancer's war is waged. Many perceive the drugs acquisition as a life and death matter, and are understandably frustrated and enraged over attempts by their government to deny them the right to decide for themselves questions of such a personal and grave nature."

The compelling nature of the health interest invoked by the plaintiff class of cancer patients falls within the spirit and intent of the privacy cases decided by this Court and the same protection should be granted them.

It should be noted that this Court's previous decision herein did not consider petitioners' rights of privacy.

CONCLUSION

Any legal right plaintiffs possess to use Laetrile may be of academic value if secured only at some undetermined future time. For the cancer victim, the phrase "justice delayed is justice denied" contains special significance. Petitioners ask simply that this Court remember that the acquisition of Laetrile for their own consumption is, for them, a matter of life and death and not one rightly governed by legal niceties. Petitioners further ask that this Court reflect on the indescribable nature of the injury they must nevertheless attempt to describe, if they are to prevail here.

This injury is clearly more than minimal or trivial; it is unconstitutional.

For the foregoing reasons, Petitioners pray that their Petition for a Writ of Certiorari be granted, and that the judgment of the United States Court of Appeals for the Tenth Circuit be reversed.

Respectfully submitted,

KIRKPATRICK W. DILLING
DENNIS M. GRONEK
ROBERT E. ARMSTRONG
188 West Randolph Street
Chicago, Illinois 60601
(312) 236-8417

KENNETH RAY COE
101 Park Avenue
Oklahoma City, Oklahoma 73102
(405) 235-8593

GLEN L. RUTHERFORD, Individually and on behalf of a class composed of terminally ill cancer patients,

Plaintiffs-Appellees,

v.

UNITED STATES OF AMERICA, Joseph A. Califano, Secretary of Health, Education and Welfare, Donald Kennedy, Commissioner of the Food and Drug Administration, et al.,

Defendants-Appellants.

No. 77-2049

United States Court of Appeals,

Tenth Circuit.

Feb. 19, 1980.

Rehearing Denied April 28, 1980.

Terminally ill cancer patients brought suit to enjoin the United States from interfering with interstate shipment of sale of laetrile on ground that it had not been approved for distribution under the Federal Food, Drug, and Cosmetic Act. After remand was ordered to the Food and Drug Administration, 582 F.2d 1234, the District Court, Luther L. Bohanon, J., 438 F. Supp. 1287, ruled in favor of plaintiffs and the Court of Appeals, 542 F.2d 1137, affirmed. On grant of certiorari,

the United States Supreme Court, 442 U.S. 544, 99 S.Ct. 2470, 61 L.Ed.2d 68, reversed and remanded. After remand, the Court of Appeals, Seth, Chief Judge, held that: (1) proponents of laetrile did not conduct the research and laboratory testing required under prevailing agency procedures and by the Act and therefore they did not meet their burden to fulfill premarketing requirements, and (2) with folk medicine aspect of use of laetrile, requirements of grandfather clause of the Act could not be met by proponents of laetrile so as to permit application of grandfather exception.

District court reversed, case remanded.

See also 424 F.Supp. 105; 429 F. Supp. 506.

Drugs and Narcotics

Although decision by a patient whether to have a treatment or not is a protected right, his selection of a particular treatment, or at least medication, is within area of governmental interest in protecting public health.

Drugs and Narcotics

Proponents of laetrile did not conduct the research and laboratory testing required under prevailing agency procedures and by Federal Food, Drug and Cosmetic Act, thus, they did not meet their burden to fulfill pre-marketing requirements. Federal Food, Drug and Cosmetic Act, Section 505, as amended 21 U.S.C.A., Section 355.

Drugs and Narcotics

With folk medicine aspect of use of laetrile, requirements of grandfather clause of Federal Food, Drug and Cosmetic Act could not be met by proponents of laetrile so as to permit application of grandfather exception. Federal Food, Drug and Cosmetic Act, Section 201(p)(1) as amended 21 U.S.C.A., Section 321(p)(1).

Barry Grossman,Atty.,Dept. of Justice, Washington,D.C.(John H. Shenefield,Asst.Atty. Genl.,Catherine G.O'Sullivan,Peter L.DeLaCruz, Atty.,Dept.of Justice,Washington,D.C.,Richard M.Cooper,Chief Counsel,Eugene M.Pfeifer,Associate Chief Counsel for Enforcement,Food and Drug Division,Dept. of Health,Education,and Welfare,Rockville,Md.,of counsel and Arnold I. Friede Asst.Chief Counsel for Enforcement,

Food and Drug Division, Dept. of Health,Education, and Welfare, Washington,D.C.,with him on brief), for defendants-appellants.

Kenneth Ray Coe of Hunt,Thomas,Dawson & Gile, Oklahoma City,Okl.(Kirkpatrick W.Dilling of Dilling,Dilling & Gronek,Chicago,Ill., Dennis M.Gronek and Robert E.Armstrong,Chicago, Ill.,of counsel,with him on brief on remand), for plaintiffs-appellees.

Charles F. Wheatley,Jr., William T. Miller and Robert A. O'Neil of Wheatley & Miller, Washington, D.C., and Grace Powers Monaco of Fairman, Frisk & Monaco, Washington, D.C., on brief, for amicus American Cancer Society, Inc.

Before SETH, Chief Judge, BARRETT and McKAY, Circuit Judges.

SETH, Chief Judge.

The case was remanded by the Supreme Court by United States v. Rutherford, 544 U.S.442, 99 S.Ct.2470,61 L.Ed.2d 68, with a reversal of our Rutherford v. United States, 582 F.2d 1234 (10th Circ.).

We had held that there was no measure or standard to permit the application of the "effective" requirement in the statute as to Laetrile as a cancer treatment by injection with a doctor's recommendation for the terminally ill patient.

The Supreme Court in its opinion held that the "effectiveness" provision of the Act did apply regardless of whether the patient was terminally ill or not. The Court also refers to those persons who have in the past (since 1907) advanced "simple and painless cures for cancer, including, lineaments of turpentine, mustard, oil, eggs, and ammonia; peatmoss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and 'Fountain of Youth' mixtures of spices, oil, and suet." The "effectiveness" of Laetrile as a <u>treatment</u> is to be demonstrated, and to be applied to those for whom no cure is presently available.

Thus, there can be no exceptions for the terminally ill; the "effectiveness" standard is so established, and we so recognize. The issues on remand are thus the application of the grandfather clauses in the two statutes, and the constitutional right of privacy. On remand, we considered the issues on the basis of the original oral arguments and briefs, and

on the briefs filed after remand.

We held in Rutherford v. United States, 542 F.2d 1137 (10th Circ.), that the FDA had the power to declare a substance a "new drug", citing Weinberger v. Hynson,Westcott & Dunning, 412 U.S.609,93 S.Ct.,2469,37 L.Ed.2d 207. We also there noted that in Weinberger the Court stated that such an order was reviewable. In Rutherford, we also stated:

> "However,the FDA has made an administrative determination that Laetrile is a new drug and this places the plaintiff in a position in which he has to admit that it is a new drug in order to get the FDA to move. As result he could not be heard to say that they have not effectively stymied the use of this drug. The FDA has done this without citing any facts whatsoever, merely a conclusion, ..."

Under these circumstances we also held:

> "We are unable, however to see how the FDA can escape the obligation of producing an administrative record to support its determination of the first and more fundamental issue that Laetrile is a new drug, for it is not a new drug merely because they say it is. Moreover, such a conclusory ruling precludes effective review under 5 U.S.C. Section 706(2)."

Also: "It seems obvious that there cannot be a court review unless there is a decent record made." The case was thus remanded to the

trial court on the new drug issue for further proceedings. Hearings by the FDA were thereafter directed by the trial court.

The FDA thereafter held what it refers to as rule-making hearings and received mostly unsworn statments although some affidavits were received. This "record" of several thousands of pages of such statements then went to the trial court and we ultimately reviewed it for Rutherford v. United States, 582 F.2d. 1234 (10th Cir.), and made some charitable remarks about it in the opinion. It must,however, be stated that our review of such a record does not necessarily mean that a similar record will again be reviewed by this court.

But as to the remaining issues, the trial court held that the petitioners had a right "to be let alone," or a constitutional right of privacy to permit them, as terminally ill cancer patients, to take whatever treatment they wished regardless of whether the FDA regarded the medication as "effective" or "safe."

(1) It would serve no useful purpose to

review the series of Supreme Court opinions treating the privacy issue. These include Whalen v. Roe, 429 U.S.589,97 S.Ct.869,51 L. Ed.64; Planned Parenthood of Missouri v. Danforth, 428 U.S.52,96 S.Ct. 2831,49 L.Ed. 788; Paris Adult Theatre I v. Slaton, 413 U.S. 49, 93 S.Ct. 2628, 37 LEd.2d 446; Roe v. Wade, 410 U.S.113,93 S.Ct. 705,35 L.Ed.2d.147; Doe v. Bolton, 410 U.S. 179,93 S.Ct.739,35 L.Ed.2d. 201; and Eisenstadt v. Baird, 405 U.S.438,92 S.Ct. 1029,31 L.Ed.2d 349. See also People v. Privitera, 23 Cal.3d 697,153 Cal.Rptr.431, 591 P.2d 919. It is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 355, is an exercise of Congressional authority to limit the patient's choice of

medication. This is clear under the decisions referred to above.

(2) The use of Laetrile is sought to be prevented because in the opinion of the Commissioner the proponents have not met the burden imposed by the agency procedures and by the statute to fulfill the premarketing requirements. These standards are impressive, but they can be, and are regularly met by the pharmaceutical houses.

It is apparent from the record that the proponents did not conduct the research and the laboratory testing required under the prevailing procedures, and it thus must be held that they did not meet their burden. The Court in Weinberger v. Hynson,Westcott & Dunning, 412 U.S. 609,93 S.Ct. 2469,37 L.Ed.2d 207, refers to the exclusion of drugs "for which there is no affirmative, reliable evidence of effectiveness." This is a reference to those FDA procedures and to the laboratory procedures.

(3) We agree with the district court that the 1938 grandfather provisions (21 U.S.C.,

Section 321(p)(1) are not applicable. The 1962 amendments added some new provisions. Public Law No. 87-781,Section 107(c)(4), 76 Stat. 788, reads in part as follows:

> "In the case of any drug, which on the day immediately preceding the enactment date (October 10,1962),(A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

It is apparent from the above quotation that the several requirements of the 1962 amendments are not in the alternative, but instead each must be met. It is also apparent that with the folk medicine aspect of the use of Laetrile the several requirements cannot be met. This is especially so as to the consistent labeling requirements since October of 1962. The record also demonstrates, not unexpectedly, that there has not been the consistency in the formula which the FDA requires under its current practice. In short,

the record does not support a conclusion that the several conditions in Pub.L.87-781 have been met to permit the application of the grandfather exceptions. In United States v. Allan Drug Corporation, 357 F.2d 713(10th Cir.), a condemnation case, we considered the 1962 amendments. We there said: "Since we are dealing with a Grandfather Clause exception, we must construe it strictly against one who invokes it."

Our mandate previously issued is recalled; the judgment of the district court is reversed, and the case remanded.

March Term - April 28, 1980

Before Honorable Oliver Seth, Chief Judge, Honorable William J. Holloway, Jr., Honorable James E. Barrett, Honorable William E. Doyle, Honorable Monroe G. McKay, Honorable James K. Logan, and Honorable Stephanie K. Seymour, Circuit Judges

GLEN L. RUTHERFORD, et al.,
Plaintiffs-Appellees
vs.
UNITED STATES OF AMERICA, et al.,
Defendants-Appellants
AMERICAN CANCER SOCIETY,
Amicus Curiae.

NO.77-2049

This matter comes on for consideration of the petition for rehearing and suggestion for rehearing en banc filed by the appellees in the captioned case.

Upon consideration whereof, the petition for rehearing is denied by the panel to whom the case was argued and submitted.

The petition for rehearing having been denied by the panel to whom the case was argued and submitted and no member of the panel nor judge in regular active service on the Court having requested that the Court be polled on rehearing en banc, Rule 35, Federal Rules of Appellate Procedure, the suggestion for rehearing en banc is denied.

Howard K. Phillips (signed)

HOWARD K. PHILLIPS, Clerk

Supreme Court, U. S.
FILED
SEP 23 1980
MICHAEL RODAK, JR., CLERK

No. 80-259

In the Supreme Court of the United States

OCTOBER TERM, 1979

GLEN L. RUTHERFORD, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

WADE H. McCREE, JR.
Solicitor General

SANFORD M. LITVACK
Assistant Attorney General

BARRY GROSSMAN
Attorney

Department of Justice
Washington, D.C. 20530
(202) 633-2217

NANCY L. BUC
Chief Counsel

JEFFREY B. SPRINGER
Deputy Chief Counsel
Food and Drug Administration
Department of Health and Human Services
Rockville, Maryland 20857

In the Supreme Court of the United States

OCTOBER TERM, 1979

No. 80-259

GLEN L. RUTHERFORD, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA, ET AL.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

QUESTIONS PRESENTED

1. Whether the court of appeals correctly determined that a group of drugs commonly referred to as Laetrile is not exempt from the premarketing clearance requirements of the Federal Food, Drug, and Cosmetic Act by operation of the Act's 1962 grandfather clause.

2. Whether the court of appeals correctly determined that the Federal Food, Drug, and Cosmetic Act does not violate any constitutional right of privacy by prohibiting the interstate distribution of Laetrile until the drug is approved as safe and effective pursuant to the Act.

---

*Pursuant to Rule 40.3 of the Rules of this Court, Patricia Roberts Harris, Secretary of Health and Human Services, and Jere E. Goyan, Commissioner of the Food and Drug Administration, are substituted for the additional respondents identified in the petition (Pet. ii).

TABLE OF CONTENTS

Page

Opinions below 1

Jurisdiction 1

Statutes involved 1

Statement 3

Argument 7

Conclusion 16

TABLE OF AUTHORITIES

Cases:

Carey v. *Population Services International*, 431 U.S. 678 ..... 14, 15

Citizens to Preserve Overton Park, Inc., v. *Volpe*, 401 U.S. 402 8

Doe v. *Bolton*, 410 U.S. 179 14

Durovic v. *Richardson*, 479 F. 2d 242, cert. denied, 414 U.S. 944 9

Griswold v. *Connecticut*, 381 U.S. 479 14

Mobil Oil Crop. v. *FPC*, 417 U.S. 283 8

Paul v. *Davis*, 424 U.S. 693 14

Planned Parenthood of Missouri v. *Danforth*, 428 U.S. 52 14

People v. *Privitera*, 23 Cal. 3d 697, 591 P. 2d 919, 153 Cal. Rptr. 431, cert. denied, 444 U.S. 949 14

Page

Cases—Continued:

Premo Pharmaceutical Laboratories, Inc. v. *United States*, No. 79-6227 (2d Cir. July 29, 1980) 9

Roe v. *Wade*, 410 U.S. 113 ..... 14, 15

United States v. *An Article of Drug * * * "Entrol-C Medicated,"* 513 F. 2d 1127 9

United States v. *41 Cases, More or Less*, 420 F. 2d 1126 10

United States v. *Johnston*, 268 U.S. 220 8

Weinberger v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 10

Weinberger v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 ..... 6, 7, 10

Whalen v. *Roe*, 429 U.S. 589 14

Statutes and regulation:

Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 7

Section 107(c)(4), 76 Stat. 789 ..... 1, 4, 7

Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, Section 201(p), 52 Stat. 1041-1042 ..... 10, 11

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* :

Section 201(p), 21 U.S.C. 321(p) 1, 4

Section 201(p)(1), 21 U.S.C. 321(p)(1) 7

Page

Statutes and regulation—Continued:

Section 201(p)(1), 21 U.S.C. (1958 ed.) 321(p)(1) 11

Section 505, 21 U.S.C. 355 ..... 1, 4

Section 505(a), 21 U.S.C. 355(a) 7

Section 505(d), 21 U.S.C. 355(d) 7

Section 505(d)(1), 21 U.S.C. 355(d)(1) 10

Section 505(i), 21 U.S.C. 355(i) 7

21 C.F.R. 310.3(h) 9

Miscellaneous:

Food Drug Cos. L. Rep. (CCH) (Jan. 28, 1980) 15

L. Goodman & A. Gilman, *The Pharmacological Basis of Therapeutics* (5th ed. 1975) 11

42 Fed. Reg. 39768-39806 (1977):

pp. 39768-39772 4

p. 39776 4

p. 39786 4

pp. 39786-39787 ..... 5, 11, 13

pp. 39787-39795 5

pp. 39788-39790 4

pp. 39790-39795 8

p. 39791 9

pp. 39791-39792 10

Page

Miscellaneous—Continued:

pp. 39792-39793 12
p. 39793 ..... 11, 12
pp. 39801-39803 4
p. 39805 13
p. 39806 5

OPINIONS BELOW

The opinion of the court of appeals on remand from this Court (Pet. App. A-1 to A-11) is reported at 616 F. 2d 455. This Court's prior decision (442 U.S. 544) reversed and remanded an earlier opinion by the court of appeals (582 F. 2d 1234) that, in turn, affirmed the district court's opinion (438 F. Supp. 1287).

JURISDICTION

The judgment of the court of appeals was entered on February 19, 1980. A petition for rehearing was denied on April 28, 1980 (Pet. App. A-13). The petition for a writ of certiorari was filed July 28, 1980. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTES INVOLVED

Section 107(c)(4) of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 789 ("1962 grandfather clause") is set forth at Pet. 4-5.

Pertinent portions of Section 201(p) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(p), are set forth at Pet. 4.

Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355, provides in part:

> (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.
>
> (b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full report reports of investigations

which have been made to show whether or not such drug is safe for use and whether such drug is effective in use * * *

* * * * *

(d) If the Secretary finds * * * that (1) the investigations * * * required to be submitted to the Secretary * * * do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests * * * do not show that such drug is safe for use under such conditions; * * * (4) * * * he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) * * * there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. * * * As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use

prescribed, recommended or suggested in the labeling or proposed labeling thereof.

* * * * *

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing * * *.

STATEMENT

This action, which was instituted by cancer patients in 1975, seeks to prevent the government from interfering with the interstate sale or distribution of a drug called Laetrile. In an order entered August 14, 1975, and amended October 10, 1975, the district court enjoined the government from preventing the purchase and subsequent interstate movement of a limited quantity of Laetrile for Glen L. Rutherford, one of the plaintiffs. *Rutherford* v. *United States*, 399 F. Supp. 1208, 1215 (W.D. Okla. 1975).[1] On appeal, the Tenth Circuit did not disturb the injunction, but instructed the district court to remand the

[1] The district court subsequently entered similar orders on behalf of other plaintiffs.

case to the Commissioner of Food and Drugs ("Commissioner") for the development of an administrative record addressing the questions whether Laetrile is a "new drug" within the meaning of Section 201(p) of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. 321(p), and, if so, whether it is exempt from the Act's premarketing approval requirements by virtue of the Act's 1962 grandfather clause. *Rutherford* v. *United States,* 542 F. 2d 1137 (10th Cir. 1976).[2]

After an administrative proceeding, the Commissioner concluded that Laetrile is a "drug" as defined in the Act, and a "new drug" within the meaning of Section 201(p) of the Act. 42 Fed. Reg. 39768-39772, 39801-39803 (1977). He found that Laetrile does not satisfy the premarketing approval requirements for new drugs in Section 505 of the Act, 21 U.S.C. 355, because it does not meet the statutory safety and effectiveness requirements. The Commissioner found that there is "an absence of scientifically sound data upon which experts * * * could base an opinion that Laetrile is safe for use in man" (42 Fed. Reg. 39786), and that "[t]here are no clinical investigations of Laetrile's effectiveness, published or otherwise, which are even arguably adequate and well-controlled" (*id.* at 39776).

---

[2]The Drug Amendments of 1962 contain a grandfather clause that excludes from the definition of "new drug" any drug that, on October 9, 1962 (the day immediately preceding the enactment of the 1962 Amendments): "(A) was commercially used or sold in the United States, (B) was not a new drug [under the 1938 Act] * * * and (C) was not covered by an effective [new drug application]." Pub. L. No. 87-781, Section 107(c)(4), 76 Stat. 789.

The Act also contains a 1938 grandfather clause (included in Section 201(p) of the Act, 21 U.S.C. 321(p)). The availability of that exemption for Laetrile is not in issue here, although it was addressed by the Commissioner and the district court. See 42 Fed. Reg. 39788-39790 (1977); *Rutherford* v. *United States*, 438 F. Supp. 1287, 1298 (W.D. Okla. 1977).

The Commissioner further found that Laetrile does not meet the statutory criteria of the 1962 grandfather clause for the following reasons: (1) The drug presently termed "Laetrile" was not shown to be the same drug used during the applicable prior period; (2) the prior labeling and representations concerning use are not identical to the representations associated with the presently marketed drugs; (3) Laetrile was not commercially used or sold on the grandfather date; and (4) experts did not generally recognize it as safe on that date. 42 Fed. Reg. 39787-39795.

On review of the Commissioner's decision, the district court upheld his determination that Laetrile is a drug, and further held (438 F. Supp. at 1293) that "the evidence of record does not render the Commissioner's conclusion that Laetrile is not 'generally recognized as safe and effective' arbitrary and capricious." The court concluded, however, that the drug is exempt from the Act's premarketing approval requirements by virtue of the 1962 grandfather clause. In reaching this conclusion, the court set aside each of the Commissioner's factual findings on the issue. 438 F. Supp. at 1295-1298. The court further concluded (438 F. Supp. at 1301; footnote omitted) that "[b]y denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right of privacy."[3]

The court of appeals, without addressing either the statutory or the constitutional ground on which the district court relied, held (582 F. 2d 1234, 1237) that "the 'safety' and 'effectiveness' requirements of the statute as

---

[3]In reaching this conclusion the court expressly rejected (438 F. Supp. at 1296-1298 nn. 18, 23-24) the Commissioner's factual finding (42 Fed. Reg. 39786-39787, 39806) that Laetrile has a known toxicity that has not been fully investigated.

now written have no application to terminally ill cancer patients who desire to take [Laetrile] intravenously."

On review, this Court reversed, holding that there is no express or implied exception from the Act for drugs used by the terminally ill. 442 U.S. 544 (1979). In reaching this decision, the Court noted the all-inclusive language of the statute (442 U.S. at 551) and congressional approval of FDA's pre-1962 policy of considering effectiveness when passing on the safety of drugs prescribed for life-threatening diseases such as cancer. 442 U.S. at 553-554 & nn.9, 10. The Court further observed (442 U.S. at 549-550) that the Commissioner applied the statutory criteria delineated in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-630 (1973), in finding that Laetrile was a new drug because it was not generally recognized as safe and effective. The Court remanded for consideration of the constitutional and grandfather clause issues reached by the district court. 442 U.S. at 559 n.18.

On remand from this Court, the court of appeals held that the proponents of Laetrile had not satisfied the Act's premarketing clearance requirements, and that the record did not support a conclusion that Laetrile satisfied the conditions of the 1962 grandfather clause (Pet. App. A-10 to A-11). Concerning the constitutional issue, the court of appeals held (*id.* at A-8) that while a patient has a right to undergo or forego medical treatment, the selection of a particular medical treatment or medication "is within the area of governmental interest in protecting public health." Thus, the Act's premarketing requirements are a legitimate exercise of congressional authority that does not offend any constitutional right of privacy (Pet. App. A-7 to A-9).

ARGUMENT

The opinion of the court of appeals is correct, consistent with prior caselaw, and presents no issue warranting a second review by this Court.

1. a. The court of appeals correctly held that the group of drugs commonly referred to as Laetrile is not exempt from the premarketing clearance requirements of the Federal Food, Drug, and Cosmetic Act by operation of the Act's 1962 grandfather clause.

That Act prohibits the introduction of any new drug into interstate commerce without approval by the Commissioner based upon adequate scientific evidence that the drug is both effective for its intended use and safe. 21 U.S.C. 355(a), (d) and 321(p)(1); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-615 (1973). (Provisions are made in Section 505(i) of the Act, 21 U.S.C. 355(i), however, for the investigational use of a new drug prior to approval.)

The effectiveness requirement was added by the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, which also included a grandfather clause that permits the continued marketing of certain established drugs that were being lawfully marketed in 1962. Those seeking to qualify a drug for exemption under the 1962 grandfather clause must establish (1) that the present drug is chemically identical to a drug in existence on the grandfather date, October 9, 1962; (2) that the drug was commercially available in 1962; (3) that the drug was generally recognized by experts as safe for its intended use; (4) that the present labeling for the drug is the same as the labeling used for it in 1962; and (5) that the drug was not covered in 1962 by an effective new drug application under the 1938 Act. Section 107(c)(4) of the Drug Amendments of 1962, 76 Stat. 789 (Pet. 4-5).

b. The Commissioner found (42 Fed. Reg. 39790-39795 (1977)) that Laetrile failed to meet all but the last of the five requirements and thus failed to qualify for an exemption under the 1962 grandfather clause. That determination is entitled to stand because, as shown below, it is supported by substantial evidence and is not arbitrary or capricious. *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 413-414 (1971).[4] In any event, review by this Court of the essentially factual questions (Pet. 18-19) raised by petitioners in their attack on the grandfather clause determination is inappropriate. See *Mobil Oil Corp.* v. *FPC*, 417 U.S. 283, 309-310 (1974); *United States* v. *Johnston*, 268 U.S. 220, 227 (1925).[5]

(1) *Composition*. First, the Commissioner properly found that the composition of the different substances referred to as Laetrile both before and after 1962 varied

---

[4]Petitioners erroneously argue (Pet. 20) that the court of appeals erred by assuming that the burden of proof with respect to the grandfather clause rested on petitioners rather than the FDA. The plain language of the grandfather clause dictates that one seeking to gain an exemption under the clause must prove that he satisfies each of its prerequisites.

A fuller discussion of the evidence and reasoning supporting the Commissioner's findings as to each of the grandfather clause requirements is contained in the Brief for the United States at 36-52, *United States* v. *Rutherford*, 442 U.S. 544 (1979).

[5]Petitioners' attacks (Pet. 20-23) on the propriety of the administrative procedures followed by the FDA are not properly before the Court. Petitioners raised such questions during the first appeals to the court of appeals, and that court acknowledged the difficulties facing the agency under the circumstances of this case and did not fault it for the procedures employed. 582 F. 2d at 1236. Petitioners did not challenge the rejection of their procedural claims in their cross-petition for a writ of certiorari, which was denied. *Rutherford* v. *United States*, 439 U.S. 1128 (1979). Moreover, they do not now present such claims as a question for review (Pet. i).

considerably, and that the 1962 formulations differed from the formulations currently in use. 42 Fed. Reg. 39791.[6] Consequently, he determined that the proponents of Laetrile had failed to sustain the burden of showing that Laetrile as presently constituted was in use on October 9, 1962. *Ibid.* As the Commissioner noted, the fact that a drug used or sold on October 9, 1962, has some ingredients in common with a drug used or sold today would not establish identity of composition sufficient to satisfy the requirements of the grandfather clause. *Ibid.* A change in any of the ingredients, including inactive ingredients, or in the proportion of the ingredients, will make a drug a "new drug." See 21 C.F.R. 310.3(h); *Premo Pharmaceutical Laboratories, Inc.* v. *United States,* No. 79-6227 (2d Cir. July 29, 1980), slip op. 4713; *United States* v. *An Article of Drug* * * * *"Entrol-C Medicated,"* 513 F. 2d 1127, 1130 n.7 (9th Cir. 1975).

(2) *Commercial availability.* Commercial availability means that the drug has been "openly and readily available and broadly distributed in the ordinary course of business" and that there was no "restriction to investigational use." *Durovic* v. *Richardson,* 479 F. 2d 242, 248 (7th Cir.), cert. denied, 414 U.S. 944 (1973). Unless a drug was available generally for commercial use on October 9, 1962, the manufacturer lacks the reliance interest recognized by Congress as warranting a grandfather exception to the requirement of effectiveness. The administrative record fully supports the Commissioner's conclusions that Laetrile, as of October 9, 1962, was not openly and readily available and was not broadly

---

[6]Laboratory analyses of drugs called Laetrile have often revealed both variances from labeled composition and variations in component parts and in the percentage of amygdalin, a principal ingredient, present (*ibid.*).

distributed in the ordinary course of business, but was in fact restricted to investigational use. 42 Fed. Reg. 39791-39792.[7]

(3) *Safety*. The 1962 grandfather clause, by its exclusion of drugs that were "new drugs" as defined in Section 201(p) of the pre-existing Act (52 Stat. 1041-1042), requires a drug to have been generally recognized as safe under its labeled conditions of use on October 9, 1962. This, in turn, requires that there must have existed on October 9, 1962, "investigations * * * includ[ing] adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use." Section 505(d)(1) of the Act, 21 U.S.C. 355(d)(1); *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973) ("the reach of scientific inquiry under both § 505(d) and § 201(p) is precisely the same"). Unless data from such tests were available in the scientific literature, there could be no basis for general recognition of safety among experts. *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra*; see also, *e.g., United States* v. *41 Cases, More or Less*, 420 F. 2d 1126, 1130 (5th Cir. 1970).

The record clearly indicates the absence in 1962 of any general recognition among qualified experts of Laetrile's safety, or indeed of any familiarity at all with the substances then referred to as "Laetrile."[8] Indeed, this

---

[7]As the Commissioner noted (42 Fed. Reg. 39791-39792) statements and actions of Dr. Ernst T. Krebs, Sr., a developer of a drug to which he gave the name "Laetrile," and his son, Ernst T. Krebs, Jr., one of Laetrile's leading proponents, make it clear that pre-1962 distribution of drugs under that name was related to investigational use and not commercial sales.

[8]One serious obstacle to general recognition of Laetrile's safety was the pre-1962 variability in its composition and the varied conditions of use recommended in its labeling, which made it impossible to identify a single, uniform drug whose composition was "generally recognized" as safe "for use under the conditions prescribed,

Court has already held, in its earlier review of this case (442 U.S. at 549), that the Commissioner correctly applied the statutory criteria in concluding that there were no adequate, well-controlled scientific studies of Laetrile's safety. The Commissioner's finding that Laetrile was not generally recognized by experts as safe on October 9, 1962, did not, however, rest solely on the absence of scientifically developed data indicative of the drug's safety. It was also based on testimony of some of the nation's leading cancer scientists that Laetrile presents significant hazards to persons to whom it is administered. 42 Fed. Reg. 39786-39787.[9]

(4) *Labeling*. The Commissioner's finding that "Laetrile as now known is not intended solely for use under conditions recommended in labeling on October 9, 1962" (42 Fed. Reg. 39793 is supported by substantial

---

recommended, or suggested in [its] labeling." Section 201(p)(1), 52 Stat. 1041-1042, 21 U.S.C. (1958 ed.) 321(p)(1); 42 Fed. Reg. 39790 (1977).

[9]Petitioners' contention (Pet. 25) that the FDA's approval of anticancer drugs with harmful side-effects demonstrates that it "has not even-handedly and non-discriminatorily applied to Laetrile the same standards by which it measures other anticancer drugs for 'safety' " is based on a misunderstanding of the applicable concept of drug safety. A drug is "safe" within the meaning of the Act if its expected therapeutic benefits outweigh the risks incurred. No drug is completely "safe" in the lay person's sense of the word, since every drug—even aspirin—involves risk. See L. Goodman & A. Gilman, *The Pharmacological Basis of Therapeutics* 325-339 (5th ed. 1975).

In the case of a drug, such as Laetrile, offered for the treatment of a life-threatening disease, lack of effectiveness not only means that there is nothing to balance against any risks: it is itself a source of risk. Patients may be led to forsake effective conventional treatments for something that will not help them. As this Court noted in its earlier opinion in this case (442 U.S. at 553-554 & nn.9, 10), the FDA's consideration of effectiveness as a criterion for the safety of drugs offered for the treatment of life-threatening diseases has congressional approval.

record evidence. *Id.* at 39792-39793. This included evidence that, in contrast to the labeling suggested by Ernst Krebs, Jr., on October 3, 1962, Laetrile was described after 1962 as a therapy that could and should be used to the exclusion of other cancer therapies. *Id.* at 39793. There was also evidence that oral administration of Laetrile first appeared after 1962 (*id.* at 39792-39793), and that suggested dosages have ranged from 1.5 grams to more than 9 grams, with no scientific rationale to account for the differing recommendations. *Ibid.* Indeed, the record indicates an absence of any uniform standard or generally recognized labeling either before or after 1962. *Ibid.*

2. In addressing the constitutional issue, the court of appeals stated (Pet. App. A-7 to A-8; citations omitted):

> It would serve no useful purpose to review the series of Supreme Court opinions treating the privacy issue * * *. It is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, is an exercise of Congressional authority to limit the patient's choice of medication. This is clear under the decisions referred to above.

Petitioners nevertheless contend (Pet. 28-42) that, in the words of the district court (438 F. Supp. at 1301; footnote omitted), "[b]y denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right of privacy." This contention lacks merit because it is based on an erroneous claim that Laetrile is nontoxic, on a

misunderstanding of the privacy interests cognizable under the Constitution, and on a failure to acknowledge the compelling governmental interests that would justify restrictions on importation and interstate distribution of Laetrile even assuming that there were a constitutional right of access to the drugs of one's choice.[10]

a. The district court's holding was premised on its unwarranted belief, contrary to the well-supported findings of the Commissioner (42 Fed. Reg. 39786-39787 (1977)), that Laetrile has been shown to be nontoxic. The court reached its conclusion by an improper reweighing of the evidence in the administrative record. It relied heavily on the anecdotal experiences of a handful of Laetrile practitioners and discounted the testimony of experts, credited by the Commissioner, which indicated that Laetrile is toxic in its oral form and that it had not been adequately tested for toxicity in any form. *Id.* at 39786-39787, 39802-39803, 39805.[11]

b. Even if Laetrile were not toxic, the court of appeals correctly held that there is no constitutional right to take any particular drug or class of drugs for medical purposes. The assertion of such a right challenges not only the Commissioner's ruling in this case but the Federal Food, Drug, and Cosmetic Act itself, as well as the centuries-old Anglo-American tradition of government protection of the public from foods and drugs that are unsafe, worthless, or fraudulent.

Petitioners essentially contend (Pet. 30, 33-39) that their asserted right of access to interstate shipments of Laetrile

---

[10]For a fuller discussion of the constitutional issue, see the Brief for the United States at 52-75, *United States* v. *Rutherford, supra.*

[11]For a fuller discussion of the toxicity question, see the Brief for the United States at 53-56, *United States* v. *Rutherford, supra.*

comes within the constitutional right of privacy recognized in *Griswold* v. *Connecticut*, 381 U.S. 479 (1965), and a subsequent line of cases that this Court has characterized as protecting the individual's interest in making independent decisions in " 'matters relating to marriage, procreation, contraception, family relationships, and child rearing and education.' " *Whalen* v. *Roe*, 429 U.S. 589, 600 n.26 (1977), quoting *Paul* v. *Davis*, 424 U.S. 693, 713 (1976).

A right of caring for one's health by obtaining a particular drug without government hindrance does not fall within any of those categories and does not involve the kind of decision with which those cases were concerned. Indeed, those cases, which concern abortion and contraception laws, make it clear that even the recognized constitutional right of privacy in matters relating to marriage and procreation may be restricted in the interest of protecting the health of the persons concerned. See, *e.g.*, *Roe* v. *Wade*, 410 U.S. 113, 154, 162-164 (1973); *Doe* v. *Bolton*, 410 U.S. 179, 189 (1973); *Planned Parenthood of Missouri* v. *Danforth*, 428 U.S. 52 (1976); *Carey* v. *Population Services International*, 431 U.S. 678, 685-686 (1977). Moreover, in *Whalen* v. *Roe*, *supra*, a case concerning government-mandated procedures for prescribing certain drugs that had both recognized therapeutic uses and a potential for abuse, this Court observed (429 U.S. at 603) that a state "no doubt could prohibit entirely" the use of such drugs. *A fortiori* where a drug like Laetrile, with some demonstrated risks and no recognized medical uses, is concerned, no constitutional right of privacy guarantees access to supplies imported or marketed through interstate commerce. See *People* v. *Privitera*, 23 Cal. 3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, cert. denied, 444 U.S. 949 (1979) (reaching the same conclusion respecting Laetrile as the court of appeals here).

c. Even if the constitutional right to privacy were held to include a right to take particular drugs for medical purposes, petitioners' claim would lack merit, because even "fundamental" rights may be restricted if the restrictions are justified by a "compelling" governmental interest. *Roe* v. *Wade, supra*, 410 U.S. at 155; *Carey* v. *Population Services International, supra*, 431 U.S. at 686.

The government has a compelling interest (1) in maintaining the confidence of the public and the medical profession in the safety and efficacy of the marketed drug supply; (2) in assuring that persons suffering from cancer, in both its early and late stages, are not deterred by the availability of an unproven drug such as Laetrile from seeking timely treatment by therapies of proven effectiveness; and (3) in assuring that cancer patients and their families are not defrauded by the promotion of costly but ineffective drugs.

Prohibiting the importation and interstate distribution of Laetrile until its safety and effectiveness are proven by reliable tests[12] is a reasonable means of effectuating those interests. And contrary to petitioners' contentions (Pet. 36-37), these restrictions are reasonable even where the drug is sought by "terminally ill" patients, a class which, as this Court has recognized (442 U.S. at 556), is almost impossible to define except in retrospect. Making available a limited supply of Laetrile to the "terminally ill" might suggest the drug had therapeutic value and induce patients who in fact have curable cancers to forsake therapies that could help them.

---

[12]The government's position is merely that Laetrile, like all other new drugs, must satisfy the requirements of the Federal Food, Drug, and Cosmetic Act before it is marketed. The Commissioner has approved an application by the National Cancer Institute to conduct clinical testing of Laetrile. See Food Drug Cos. L. Rep. (CCH) para. 40,084 (Jan. 28, 1980).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

WADE H. MCCREE, JR.
Solicitor General

SANFORD M. LITVACK
Assistant Attorney General

BARRY GROSSMAN
Attorney

NANCY L. BUC
Chief Counsel

JEFFREY B. SPRINGER
Deputy Chief Counsel
Food and Drug Administration
Department of Health and Human Services

SEPTEMBER 1980

DOJ-1980-09

MOTION FILED
SEP 19 1980

No. 80-259

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

GLEN L. RUTHERFORD, *et al.*,
Petitioners

v.

UNITED STATES OF AMERICA, *et al.*,
Respondents

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, INC. IN OPPOSITION TO THE PETITION FOR CERTIORARI

GRACE POWERS MONACO
BARRY R. LENK
FAIRMAN, FRISK & MONACO
2025 Eye Street, N.W.
Suite 1022
Washington, D.C. 20006
202/296-3785

Attorneys for the American Cancer Society, Inc.

September 19, 1980

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

No. 80-259

GLEN L. RUTHERFORD, *et al.*,
Petitioners

v.

UNITED STATES OF AMERICA, *et al.*,
Respondents

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Tenth Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The American Cancer Society, Inc. ("Society") respectfully requests leave to file *instanter* the written brief *amicus curiae* in support of the United States' opposition to the petition for writ of certiorari. The interest of the Society and a chronology of its participation in the proceedings involving laetrile which preceded and are related to this petition for certiorari are detailed on the "Statement of Interest" in the attached brief. Succinctly stated the Society participated (a) in the laetrile rule-

making proceeding before the Food and Drug Administration; (b) as *amicus curiae* without opposition in the proceedings before the United States Court of Appeals for the Tenth Circuit which were reviewed on petition for certiorari by this Court in Docket No. 78-605; *United States* v. *Rutherford;* and (c) this Court on motion permitted the Society to participate as *amicus curiae* in the proceedings in Docket No. 78-605 which resulted in this Court's opinion of last June, 442 U.S. 544.

By letter of August 18, the Society requested a letter of consent to participate as *amicus curiae* from the United States and from Petitioner Rutherford.

By letter of August 25, 1980, the Solicitor General of the United States, Wade H. McCree, Jr., consented to the filing of a brief *amicus curiae* on behalf of the American Cancer Society in the Supreme Court in this case.

On September 12, counsel attempted to reach Kirkpatrick Dilling, one of the counsel for Petitioner Rutherford, to ascertain why no response had been received to the Society's letter of August 18 requesting permission to participate as *amicus curiae* in this proceeding. Counsel was informed that Mr. Dilling was out-of-the-country until September 24, 5 days after the date on which the Society's brief would have to be filed with this Court. However, Mr. Gronek, one of Mr. Dilling's partners, agreed to check his files for any instructions relating to the Society's request. By telephone conversation of September 15, Mr. Gronek stated that he would be unwilling to make a decision for his partner and that the question would be referred to Mr. Dilling on his return.

On September 12, 15 and 16, counsel also telephoned the office of Kenneth Coe, another of Petitioner's Counsel. Although repeated messages were left requesting a response to the Society's letter seeking consent to participate as *amicus curiae*, Mr. Coe did not return these calls.

While the Society supports the position of the Petitioner, the United States, its brief presents a different perspective, one which is in keeping with the role of the Society.

The Society is a voluntary organization fighting cancer through balanced programs of research, education, patient service and rehabilitation. The American public and the medical profession look to the Society for the most up-to-date and accurate information about cancer. Without the widespread dissemination of accurate information, such as that provided by the Society, the goal of further reducing the ravages of cancer through early diagnosis and treatment would unquestionably be more difficult to achieve.

Inasmuch as early and proper treatment of cancer is a life-and-death matter, unjustified deviations from this desideratum are of concern to the Society. One of the areas in the forefront of public and professional questioning addressed to the Society pertains to unproven methods of cancer management, e.g. laetrile.

It is from this perspective that the Society approaches participation as an *amicus curiae* in this proceeding. The Society's brief is not a repetition of arguments made by the Petitioner or, we anticipate, by the United States, but rather deals with and contains matter related to the impact of the Court of Appeals decision requiring application of the premarketing clearance provisions of the federal drug laws to laetrile both on the terminally ill as well as on those with life-threatening illness. The Society's brief deals with the issues of the role of the federal government with respect to the regulation of drugs in a manner and from a viewpoint different from that of the other parties.

The Society believes, in view of the nature of the case at bar, and the arguments urged or anticipated from the

parties, that its arguments and information will assist the Court in its decision on the petition and that the Society should therefore be granted leave to file its brief *amicus curiae* in support of the Government.

Respectfully submitted,

GRACE POWERS MONACO
BARRY R. LENK
FAIRMAN, FRISK & MONACO
2025 Eye Street, N.W.
Suite 1022
Washington, D.C. 20006
202/296-3785

Attorneys for Amicus Curiae, the American Cancer Society, Inc.

September 19, 1980

TABLE OF CONTENTS

	Page
STATEMENT OF INTEREST OF THE AMERICAN CANCER SOCIETY	1
REASONS FOR DENYING THE PETITION FOR WRIT OF CERTIORARI	4
I. THE FEDERAL APPEAL'S COURT DECISION ON THE PROCEDURAL ISSUES RAISED BY PETITIONERS IS IN ACCORD WITH ACCEPTED JUDICIAL PROCEDURE AND WITH THE DECISIONS OF THIS COURT AND OTHER FEDERAL APPELLATE COURTS	4
A. Introduction	4
B. Petitioners Claim That The Absence Of An Opportunity For Cross Examination Is Grounds For Reversing The Decision Of The Federal Appeals Court Finds No Support In The Legal Authority Relied Upon And Conflicts With The Basic Principles Of Administrative Procedure	5
C. Petitioners' Objection That The FDA Hearing Was Conducted By The Most Informal Procedures Allowed Is Factually Incorrect; The Procedure Selected Represents A Legitimate Exercise Of Agency Discretion	6
D. Petitioners' Objection That The Record Compiled By The Food And Drug Administration Did Not Meet The Standards Set Forth By The Federal Appeals Court Is Refuted By The Court Of Appeals' Willingness To Review This Record	7
E. The Federal Appeals Court Properly Placed The Burden Of Proof Upon Petitioners To Demonstrate That Laetrile Was Subject To The Grandfather Clause Of The 1962 Act	8

TABLE OF CONTENTS—Continued

Page

II. THE FEDERAL APPEALS COURT HAS DECIDED THE GRANDFATHER CLAUSE AND RIGHT OF PRIVACY ISSUES IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF ITS SISTER FEDERAL APPEALS COURTS ON THE SAME ISSUES 10

A. The Petitioners Do Not Set Forth Any Actions Of The Federal Appeals Court Pertaining To Disposition Of The Grandfather Issue That Warrants Review By This Court.. 10

1. Petitioners Inappropriately Seek Review of Factual Findings; Petitioners Allege Appeals Court Error On Only One Of The Four Criteria Which Must Be Met To Receive Coverage Of The Grandfather Clause 10

(a) Safety 11

(b) Commercial Use And Sale 12

2. The Federal Appeals Court Has Decided The Grandfather Issue In Accordance With The Provisions Of The Federal Drug Laws 12

II. THE FEDERAL APPEALS COURT HAS DECIDED THE RIGHT OF PRIVACY ISSUE IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF THIS COURT 14

CONCLUSION 20

TABLE OF AUTHORITIES

Court Cases	Page
Diamond King Ranch, Inc. v. *Morton*, 531 F.2d 1397 (10th Cir. 1976)	12
Doe v. *Bolton*, 410 U.S. 179 (1973)	16
Durovic v. *Richardson*, 479 F.2d 242 (7th Cir. 1973), *cert. denied*, 414 U.S. 944 (1973)	11
Eisenstadt v. *Baird*, 405 U.S. 438 (1972)	16, 19
FTC v. *American Tobacco Co.*, 274 U.S. 543 (1927)	8
FTC v. *Standard Oil Co.*, 355 U.S. 396 (1958)	8
General Talking Pictures Corp. v. *Western Electric Company*, 304 U.S. 175 (1938)	10
Julian H. Morgan Sr. v. *David Matthews*, Civil Action No. 76-1636 (D.S.C.), Opinion of Judge Chapman, Nov. 30, 1976	9
NLRB v. *Pittsburgh Steamship Co.*, 340 U.S. 498 (1951)	8
National Labor Relations Board v. *Waterman Steamship Corp.*, 309 U.S. 206 (1940)	10
North American Pharmacal, Inc. v. *HEW*, 491 F.2d 546 (8th Cir. 1973)	9
Paris Adult Theatre I v. *Slaton*, 413 U.S. 49 (1973)	16
People v. *Privitera*, 23 Cal. 3rd 697, 153 Cal. Rptr. 431, 591 P.2d 919 (Cal. 1979), *cert. denied*, 444 U.S. 949 (1979)	15, 16
Planned Parenthood of Missouri v. *Danforth*, 428 U.S. 52 (1976)	16
Roe v. *Wade*, 410 U.S. 113 (1973)	16, 17
Rutherford v. *American Medical Association*, 379 F.2d 641 (7th Cir. 1967), *cert. denied*, 389 U.S. 1043	9
Rutherford v. *United States*, 542 F.2d 1137 (10th Cir. 1976)	7, 8, 9
Rutherford v. *United States*, 438 F. Supp. 1287 (W.D. Okla. 1977) affirmed on other grounds, 582 F.2d 1234 (10th Cir. 1978), reversed and remanded, 442 U.S. 544 (1979) opinion reversing district court on remaining grounds, 616 F.2d 455 (1980)	2, 4, 7, 9, 14, 15

TABLE OF AUTHORITIES—Continued

	Page
Sabin v. *Butz*, 515 F.2d 1061 (10th Cir. 1975)	13
Socialist Labor Party v. *Gilligan*, 406 U.S. 583 (1972)	12
Tutoki v. *Celebreeze*, 375 F.2d 105 (7th Cir. 1967)	9
Ubiotica Corp. v. *FDA*, 427 F.2d 376 (6th Cir. 1970)	9
United States v. *Allan Drug Corp.*, 357 F.2d 713 (10th Cir. 1966), *cert. denied*, 385 U.S. 899 (1966)	9, 11
United States v. *An Article of Drug . . . Bentex Ulcerine . . .*, 469 F.2d 875 (5th Cir. 1972), *cert. denied*, 412 U.S. 938 (1973)	11
United States v. *Florida East Coast Ry.*, 410 U.S. 224 (1973)	7
United States v. *Johnson*, 268 U.S. 220 (1925)	10
United States v. *1,048,000 Capsules, More or Less*, 347 F. Supp. 768 (S.D. Tex. 1972), aff'd, 494 F.2d 1158 (5th Cir. 1974)	11
USV Pharmaceutical Corp. v. *Weinberger*, 412 U.S. 655 (1973)	9
Universal Camera Corp. v. *NLRB*, 340 U.S. 474 (1951)	8
Upjohn Co. v. *Finch*, 422 F.2d 944 (6th Cir. 1970)	9
Vermont Yankee Nuclear Power Corp. v. *Natural Resources Defense Council, Inc.*, 435 U.S. 519 (1978)	7
Weinberger v. *Bendex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973)	9
Weinberger v. *Hynson, Wescott and Dunning, Inc.*, 412 U.S. 609 (1973)	9
Whalen v. *Roe*, 429 U.S. 589 (1977)	16, 18

Statutes

The Administrative Procedure Act, 5 U.S.C. 556(b), 5 U.S.C. 556(d)	5, 6
15 U.S.C. 401 *et seq.*	6
15 U.S.C. 1451 *et seq.*	6

TABLE OF AUTHORITIES—Continued

Page

The Federal Food, Drug and Cosmetic Act, as amended ..... *passim*

21 U.S.C. 321 *et seq.* 6

The Drug Amendments of 1962,

Public Law No. 87-781 (76 Stat. 789), Sec. 107(c)(4) 11

Miscellaneous Statutory Authority for FDA Rules of Practice and Procedure

21 U.S.C. 40-41 6
21 U.S.C. 141-149 6
21 U.S.C. 679(b) 6
21 U.S.C. 821 *et seq.* 6
21 U.S.C. 1031 et seq. 6
42 U.S.C. 201 *et seq.* 6
42 U.S.C. 257a 6

Code of Federal Regulations

Food and Drug Administration Rules of Practices and Procedures 6

21 C.F.R. 10.1(a) 6
21 C.F.R. 10.60 6
21 C.F.R. 10.60(c)(1) 6
21 C.F.R. 10.60(c)(7) 7
21 C.F.R. 10.65 7

Federal Register

FDA Practices and Procedures, 42 Fed. Reg. 4706 (1977) (subsequently codified in 21 C.F.R. 10.60) 6

Notice of Rulemaking Proceeding, 42 Fed. Reg. 10066 *et seq.* (1977) 5

FDA Commissioner's Decision on Laetrile Rulemaking Proceeding, 42 Fed. Reg. 39768 (1977) .. 11, 13, 17, 18

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

No. 80-259

GLEN L. RUTHERFORD, *et al.*,
Petitioners

v.

UNITED STATES OF AMERICA, *et al.*,
Respondents

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Tenth Circuit

BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, INC. IN OPPOSITION TO THE PETITION FOR CERTIORARI

STATEMENT OF INTEREST OF THE AMERICAN CANCER SOCIETY

The American Cancer Society has a substantial interest in the outcome of this proceeding. Briefly stated, the American public and the medical profession look to the American Cancer Society and its 58 chartered Divisions and 2,964 local units, to provide the most up-to-date and accurate information about cancer. In most

cases early and effective treatment of cancer is a life and death matter. One of the major concerns expressed by the public and the medical profession in questions addressed to the Society pertains to unproven methods of cancer treatment. To respond to the need for information in this area the Society has established a committee on unproven methods and maintains one of the world's largest reference centers for the collection and dissemination of data concerning cancer. To further its obligation to the public and the medical profession to uncover and disseminate the facts relating to unproven methods of cancer treatment, the Society participated in the Rutherford proceedings on the rulemaking level [1] and in the capacity of *amicus curiae* in the proceedings on appeal which are the subject of this petition including the appeal which was resolved by this court's decision of June 18, 1979, in *Rutherford* v. *United States*, 442 U.S. 544.

Mr. Rutherford's petition challenges the existing statutory protection against ineffective methods of cancer treatment contained in state and federal drug laws. If the current requirements of safety and efficacy fall, the patient/consumer and the practicing physician will be deprived of their first line of defense against ineffective drugs. It is as true today as it was when President Kennedy requested legislation assuring the efficacy of drugs that:

> . . . There is no way of measuring the needless suffering, the money innocently squandered, and the protraction of illnesses resulting from the use of . . . . ineffective drugs.

---

[1] Rutherford v. United States, 438 F. Supp. 1287 (W.D. Okla. 1977) affirmed on other grounds, 582 F.2d 1234 (10th Cir. 1978) reversed and remanded, 442 U.S. 544 (1979) opinion reversing district court on remaining grounds, 616 F.2d 455 (1980).

> The physician and consumer should have the assurance from an impartial scientific source that any drug or therapeutic device on the market today is safe and effective for its intended use . . . .[2]

The impact of the Appeals Court's decision which prevents circumvention of federal drug standards of safety and efficacy by either a "right of privacy" or grandfathering rationale will obviously affect the Society in its role as a primary source of information for the general public and the medical profession for accurate information on unproven methods of cancer treatment.

In sustaining the validity of the pre-marketing clearance requirements of the federal drug laws, the Court of Appeals has effectively closed one of the floodgates that would encourage the marketing of an unproven cancer treatment. The decision affirms a reasonable pre-market standard. It protects victims of cancer, who, when confronted with a life-threatening illness, are particularly susceptible to cures promised by use of a worthless and therefore unsafe and dangerous drug. The Society's interest lies in speaking out for the continuation of the proper balance of manufacturer and consumer interest which currently exists in the statutory scheme regulating drugs. It would be a great disservice to the public if a decision affirming the balanced regulatory scheme was undermined by a petition which, as demonstrated below, is unsound as a matter of law.

The American Cancer Society has received the consent of counsel for the United States to file this brief *amicus curiae* in accordance with Rule 42 of this Court. That permission is attached to the original of this brief filed with the Supreme Court.

---

[2] Statement of John F. Kennedy to Congress, March 15, 1962, in support of the 1962 Amendment to the Federal Food, Drug and Cosmetic Act. 108 Cong. Rec. 4169, 1962 U.S. Code Cong. & Admin. News at 4143.

REASONS FOR DENYING THE PETITION FOR WRIT OF CERTIORARI

I. THE FEDERAL APPEAL'S COURT DECISION ON THE PROCEDURAL ISSUES RAISED BY PETITIONERS IS IN ACCORD WITH ACCEPTED JUDICIAL PROCEDURE AND WITH THE DECISIONS OF THIS COURT AND OTHER FEDERAL APPELLATE COURTS

A. Introduction

Petitioners claim that the administrative proceeding by the Food and Drug Administration to determine whether laetrile meets the requirements of the Food, Drug and Cosmetic Act was improperly conducted. Petitioners allege that the procedure utilized in this hearing violated statutory protections and constituted an abuse of discretion by the Food and Drug Administration (hereinafter "FDA"). The analysis of specific arguments advanced by petitioners reveals not only that the proceedings was conducted within the bounds of statutory requirements and agency discretion, but that Petitioners failed to object to the procedures proposed to be employed by the FDA spelled out in notices in the Federal Register prior to the proceeding's commencement. Thus, the Petitioners did not, by appropriate comment in advance of hearing, provide the agency with an opportunity to modify any procedures it argued were defective. Petitioners are now attempting to profit from their silence by raising these issues before the Court.[3]

---

[3] These issues were also raised in briefs to the Federal Appeals Court and to this court on certiorari in United States v. Rutherford, 582 F.2d 1234 (10th Cir. 1978) revised and remanded, 442 U.S. 544 (1979). See e.g. Brief of Respondents before this court in Docket No. 78-605, pp. 29-30. It is questionable whether Petitioners still have standing to raise them here.

B. Petitioners' Claim that the Absence of an Opportunity for Cross Examination is Grounds for Reversing the Decision of the Federal Appeals Court finds no Support in the Legal Authority Relied Upon and Conflicts with the Basic Principles of Administrative Procedure

Petitioners allege that the denial of an opportunity for cross-examination "belied any openminded review by the Food and Drug Administration." (Petitioner's Brief, p. 21) Yet, Petitioners hands are far from clean on this issue. On February 8, 1977, a notice was placed in the Federal Register detailing the procedures to be used by the FDA and announcing that oral argument was scheduled on May 2, 1977.[4] During the interim, petitioners failed to object to these announced procedures. Only at the last stage of the rulemaking procedure—the hearing in Kansas to take testimony by oral argument, did the Petitioners object.[5] Petitioners should not be permitted to profit from their silence by obtaining a writ of certiorari on this basis.

Moreover, petitioners are incorrect in their assertion that the Administrative Procedure Act establishes a right to cross-examination in this proceeding. (Petitioners Brief, p. 22) Petitioners rely upon 5 U.S.C. 556(d) to establish their alleged right to cross-examination in this proceeding. Section 556(b) clearly states that "[T]his subchapter does not supersede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute." 5 U.S.C. 556(b)

The Administrative Procedure Act explicitly provides that it shall not supersede hearing procedures established pursuant to another statute. The hearing in question

---

[4] 42 Federal Register 10066 et seq. (1977).

[5] TR. 10.

took place pursuant to § 2.14 of the FDA's Practices and Procedures (42 Fed. Reg. 4706) which is currently incorporated in the Code of Federal Regulations as 21 C.F.R. 10.60. These Administrative Practices and Procedures have been promulgated pursuant to extensive statutory authority,[6] including but not limited to the Food, Drug and Cosmetic Act.[7]

Because § 2.14 empowers the Commissioner, in the exercise of discretion, to conduct hearings on matters referred by courts without providing for cross-examination, this source of authority supersedes any conflicting requirements of the Administrative Procedure Act. Petitioners' reliance upon the Administrative Procedure Act to object to the FDA proceeding is therefore misplaced.

C. Petitioners' Objection that the FDA hearing was Conducted by the most Informal Procedures Allowed is Factually Incorrect; the Procedure Selected Represents a Legitimate Exercise of Agency Discretion

Petitioners allege that the lack of an openminded review by the Food and Drug Administration is evidenced by the Commissioner's decision to conduct hearings under provisions for the most informal proceedings allowed. (p. 21) This statement is inaccurate. Under 21 C.F.R. 10.60(c), the Commissioner may use his discretion to employ less formal procedures than those which were used, to reach a determination on matters referred by federal, state, or local courts. For example, 21 C.F.R. 10.60(c)(1) permits a determination by conferences,

---

[6] 21 U.S.C. 321 *et seq.*; 42 U.S.C. 201 *et seq.*; 42 U.S.C. 257a; 21 U.S.C. 821 *et seq.*; 21 U.S.C. 679(b); 21 U.S.C. 1031 *et seq.*; 21 U.S.C. 141-149; 21 U.S.C. 41-40; 15 U.S.C. 401 *et seq.*; 15 U.S.C. 1451 *et seq.* Statutory Authority pursuant to which FDA Rules of Practice and Procedure were promulgated.

[7] 21 C.F.R. 10.1(a).

meetings, discussions, and correspondence pursuant to 21 C.F.R. 10.65. In addition, 21 C.F.R. 10.60(c)(7) permits a determination based upon data, information, and views with no oral testimony received pursuant to the publication of a notice in the Federal Register.

The proceedings employed by the Commissioner were not the least formal method of review as Petitioners allege. These hearing procedures represented a legitimate exercise of agency discretion in choosing a set of hearing procedures best suited to assist the Commissioner in reaching a decision given the diverse nature of the consumer, scientific, medical population concerned as well as the folk medicine nature of the drug involved. It is not the function of the Court to second-guess the exercise of discretion legitimately exercised under agency regulations.[8]

D. Petitioners' Objection that the Record Compiled by the Food and Drug Administration did not Meet the Standards Set Forth by the Federal Appeals Court is Refuted by the Court of Appeal's Willingness to Review this Record

Petitioners assert that the FDA's administrative hearing did not meet the standards set forth by the United States Court of Appeals for the Tenth Circuit, 542 F.2d 1137, 1143-4 (10th Cir. 1976) (Petitioners Brief, pp. 21-22). However, recognizing that laetrile is an alleged folk medicine with no established or organized proponents, the Court of Appeals found that the 5,500 pages of written submissions and two days of oral hearings constituted an acceptable record and proceeded to so review it. *Rutherford* v. *United States*, 616 F.2d 455, 456 (10th Cir.), see also 582 F.2d 1234, 1236 (10th Cir. 1978).

---

[8] Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519 (1978); United States v. Florida East Coast Ry., 410 U.S. 224 (1973).

The FDA's record was deemed acceptable for review by the Tenth Circuit. That court has not been shy in the past to turn away records which it did not deem acceptable for review. That court mandated the laetrile rulemaking proceeding because it considered the record presented for review on laetrile was insufficient.[9] The appeals court did not find the laetrile rulemaking proceeding record similarly insufficient. It is not the function of the Supreme Court to substitute its own opinion for that of the Court of Appeals in reviewing the record.[10] Petitioner's request that this Court second-guess the Court of Appeals on the adequacy of the record therefore exceeds the proper scope of review by this Court.

E. The Federal Appeals Court Properly Placed the Burden of Proof Upon Petitioners to Demonstrate that Laetrile was Subject to the Grandfather Clause of the 1962 Act

Petitioners object that the Federal Appeals Court improperly shifted the burden of proof involving whether laetrile met the requirements of the grandfather clause from the FDA to Petitioners. (Petitioner's Brief, p. 20) There is no error on this issue in the Federal Appeals Court opinion.

The federal appeals court at the interlocutory stage of this proceeding at which it remanded for a rulemaking proceeding had, in *dicta*, stated that "[T]o support its determination [that laetrile is a new drug] the FDA in the case at bar would have to present substantial evidence to support the proposition that laetrile is not gen-

---

[9] Rutherford v. United States, 542 F.2d 1137, 1143-3 (10th Cir. 1976).

[10] NLRB v. Pittsburgh Steamship Co., 340 U.S. 498 (1951); FTC v. Standard Oil Co., 355 U.S. 396 (1958); Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951); FTC v. American Tobacco Co., 274 U.S. 543 (1927).

erally recognized among qualified experts as 'safe and effective,' and that laetrile is not grandfathered . . . ." 542 F.2d 1137 at 1143 (10th Cir. 1976). That *dicta*, relied on by Petitioners, did not represent the decisions of this Court,[11] and was in conflict with the decisions of other federal courts passing upon the same issue.[12]

No matter how a drug becomes the subject of an FDA rulemaking proceeding either by agency initiative, manufacturer or other drug proponent initiative or court referral, the burdens of proof and proceeding and the standards of review established by the federal drug laws as construed by the courts are the same. The statute and regulations do not require the Food and Drug Administration to prove a drug ineffective but rather, the burden of proceeding and proof of safety/efficacy by a substantial amount of well documented evidence lies with the proponents of the drug.[13]

---

[11] See e.g. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 617 (1973); Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652 (1973); USV Pharmaceutical Corp. v. Weinberger, 412 U.S. 655, 660 (1973). Nor does it represent other federal decisions relied upon by this court. See e.g. Ubiotica Corp. v. FDA, 427 F.2d 376, 378 (6th Cir. 1970); Upjohn Co. v. Finch, 422 F.2d 944, 955 (6th Cir. 1970); North American Pharmacal, Inc. v. HEW, 491 F.2d 546, 550-51 (8th Cir. 1973).

[12] See e.g., Julian H. Morgan, Sr. et al. v. David Matthews et al., Civil Action No. 76-1636 (D. South Carolina) Opinion of Judge Chapman, November 30, 1976 (laetrile case); Tutoki v. Celebreeze, 375 F.2d 105 (7th Cir. 1967) (krebiozen); Rutherford v. American Medical Ass'n, et al., 379 F.2d 641 (7th Cir. 1967) (cert. den., 389 U.S. 1043). See also H. Rept. No. 2139, 75th Cong., 3rd Session (April 14, 1938) at p. 9 and H.R. Rept. No. 2464, 87th Cong., 2nd Sess. (Sept. 22, 1962) pp. 3, 5 which make it clear that the burden of presenting evidence that a product is not a new drug lies with the manufacturer.

[13] See Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) citing United States v. Allan Drug Corporation, 357 F.2d 713 (10th Cir. 1966), cert. denied, 385 U.S. 899 (1966).

The Federal Appeals Court corrected its prior error by the opinion before this Court on petition for certiorari. The appeals court properly held that the statute, case law and agency procedures all place the burden of proof upon the party seeking the grandfather clause exception.[14]

II. THE FEDERAL APPEALS COURT HAS DECIDED THE GRANDFATHER CLAUSE AND RIGHT OF PRIVACY ISSUES IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF THIS COURT AND IN CONCERT WITH THE DECISIONS OF ITS SISTER FEDERAL APPEALS COURTS ON THE SAME ISSUES

A. The Petitioners do not Set Forth Any Actions of The Federal Appeals Court Pertaining to Disposition of the Grandfather Clause Issue that Warrant Review by This Court

1. *Petitioners Inappropriately Seek Review of Factual Findings; Petitioners Allege Appeals Court Error on Only One of the Four Criteria Which Must be Met to Receive Coverage of the Grandfather Clause*

It is a well settled position of this Court that it will not ordinarily grant certiorari to review evidence, discuss specific facts or to review judgments based solely on questions of fact. See e.g., *United States* v. *Johnson*, 268 U.S. 220 (1925), *General Talking Pictures Corp.* v. *Western Electric Company*, 304 U.S. 175 (1938) and *National Labor Relations Board* v. *Waterman Steamship Corp.*, 309 U.S. 206 (1940). Yet this is exactly the activity which Petitioner would have the Court undertake. Petitioners' substantive[15] attack on the appeals court's

---

[14] See notes, *supra*.

[15] The procedural objections by Petitioners to the federal appeals court's application of the grandfather clause are covered in Part I of this brief, *supra*.

application of the criteria in the grandfather clause contained in the 1962 Amendments relates to matters of fact:

> "Appeal Court's recent opinion herein misconstrues the factual circumstances and also the factors involved as to the "grandfathering" of Laetrile, or amygdalin . . . ." Petitioners Brief at p. 18.

Then, although the 1962 grandfather clause contains four criteria [16] all of which must be satisfied to invoke its coverage,[17] Petitioner alleges appeal court error of fact on only one of the grandfather requirements, that relating to consistency in formula. See Petitioner's Brief at page 18. As to the other grandfather criteria:

(a) *Safety*

Petitioner refers to the findings of the district court which it considers preferable on the "safety" criteria. See Petitioners Brief at pp. 23-24. However, Petitioners

---

[16] Entitlement to the grandfather exemption of the 1962 amendments, *i.e., Section 107(c)(4) of the Food and Drug Act,* is limited to drugs which: (1) feature *today* the identical chemical composition recommended dosages, and claims made in labeling as existed on October 9, 1962, and (2) were used or sold commercially in the United States on October 9, 1962, and (3) were generally recognized by the experts as safe; and (4) were not covered by an effective drug application. See United States v. Allan Drug Corp., 357 F.2d 713, 718-19 (10th Cir. 1966), cert. denied, 385 U.S. 899; United States v. 1,048,000 Capsules, More or Less, 347 F. Supp. 768 (S.D. Tex. 1972), aff'd 494 F.2d 1158 (5th Cir. 1974); see also Rutherford v. United States, 542 F.2d 1137, 1141 (10th Cir. 1976). The Commissioner concedes issue No. 4 in the Notice of Rulemaking.

[17] See e.g. United States v, Allan Drug Corp., *supra.* Accord Durovic v. Richardson, 479 F.2d 242, 250 n.6 (7th Cir. 1973), cert. denied, 414 U.S. 944 (1973); United States v. An Article of Drug . . . Bentex Ulcerine . . ., 469 F.2d 875, 878 (5th Cir. 1972), cert. denied, 412 U.S. 938 (1973); United States v. 1,048,000 Capsules, More or Less, et al., 347 F. Supp. 768, 770 (S.D. Tex. 1972), aff'd 494 F.2d 1158 (5th Cir. 1974).

make no attempt to set forth let alone support any error in the differing Federal Appeals Court's finding on this issue.

(b) *Commercial Use and Sale*

Petitioners do not even address the "commercial use and sale" requirement of the grandfather clause.

As noted above, all grandfather criteria must be met to gain the coverage of the clause. Petitioners have identified an alleged defect in the appeals court's opinion only as to one of the clause's criteria.[18] This solitary alleged error is factual and would not support review even if correct. Petitioners have not specified findings of the appeals court in error on the rest of the grandfather clause criteria which must be satisfied to gain the relief sought, Petitioners do not make a showing which warrants review by or relief from this Court.

2. *The Federal Appeals Court has Decided the Grandfather Issue in Accordance with the Provisions of the Federal Drug Laws*

Petitioners' pleading, as set forth in the preceding section, does not articulate reasons supporting a grant of certiorari. Moreover, scrutiny of the appeals courts decision against accepted standards of review and the record before the court demonstrate that there is no error in that court's action.

The Commissioner's Laetrile Rulemaking decision is subject to the standards of court scrutiny applicable to review of agency action. The review court is required to view the record as a whole[19] and determine whether

---

[18] The Society submits that the issues are not presented with the detail or the clarity needed for effective adjudication and that review is not appropriate. See Socialist Labor Party v. Gilligan, 406 U.S. 583 (1972).

[19] See Diamond King Ranch, Inc. v. Morton, 531 F.2d 1397, 1405 (10th Cir. 1976).

the Commissioner had articulated the grounds of his decision, whether those grounds are consistent with the statute, and whether those grounds are supported by the evidence of record. In short, if the Commissioner's decision shows that the FDA has a reasonable basis for considering that the drug proponent's submissions did not comply with the substantial evidence requirements of the statute and regulations, the Commissioner's decision should be affirmed.[20] The 10th Circuit articulated this standard for review in *Sabin* v. *Butz*.[21]

> . . . . the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency. Id. The court's function is exhausted where a rational basis is found for the agency action taken. Udall v. Washington, Maryland, and Virginia Coach Co., 130 U.S. App. D.C. 171, 398 F.2d 765, 769, cert. denied, Washington Metropolitan Area Transit Com. v. United States, 393 U.S. 1017, 89 S.Ct. 620, 622, 21 L.Ed. 2d 561.

Application of this standard of proof and review criteria supports the conclusion reached by the Commissioner, and affirmed by the appeals court's reversal of the district court's findings, namely that the drug Laetrile does not satisfy any of the elements of the 1962 grandfather clause:[22]

> It is apparent . . . that the several requirements of the 1962 amendments are not in the alternative, but instead each must be met. It is also apparent that with the folk medicine aspect of the use of Laetrile the several requirements cannot be met.

---

[20] Sabin v. Butz, 515 F.2d 1061, 1067 (10th Cir. 1975).

[21] Id.

[22] See generally on the lack of general recognition of safety/efficacy; inconsistency in formulation, dosages and labelling claims and investigational as opposed to commercial use, the Commissioners Opinion, 42 Fed. Reg. at pp. 39790-39795.

> This is especially so as to the consistent labeling requirements since October of 1962. The record also demonstrates, not unexpectedly, that there has not been the consistency in the formula which the FDA requires under its current practice. In short, the record does not support a conclusion that the several conditions in Pub.L. 87-781 have been met to permit the application of the grandfather exceptions. In United States v. Allan Drug Corporation, 357 F.2d 713 (10th Cir.), a condemnation case, we considered the 1962 amendments. We there said: "Since we are dealing with a Grandfather Clause exception, we must construe it strictly against one who invokes it." [23]

Petitioners have not demonstrated any error that requires this Court to grant certiorari.

III. THE FEDERAL APPEALS COURT HAS DECIDED THE RIGHT OF PRIVACY ISSUE IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF THIS COURT

Petitioners seek an exemption for the terminal in choosing laetrile on constitutional grounds that parallel the exemption by statutory construction rejected by this Court in its *Rutherford* opinion. 442 U.S. 544 (1979) This Court in the closing paragraph of *Rutherford* states that the Act's

> "explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective reinforces our conclusion that no exception for terminal patients may be judicially implied."

Although this analysis deals with statutory construction, its rationale is equally persuasive against the background of this Court's decisions on a right of privacy vis a vis choices of medical treatment. Cancer victims constitute

---

[23] Rutherford v. U.S., 616 F.2d 455, 457.

a minority in our society; terminal cancer patients constitute an even smaller minority, but like other groups, they have a right not to be exploited. In the case of cancer drugs, particularly the exercise of government power of protection, premarket clearance is not only reasonable, but necessary to protect the compelling public interest in effective cancer therapy, and in assuring that non-therapeutic drugs do what they say. In view of the widespread incidence of cancer, the serious consequences of the disease, the experience with the particular vulnerability of cancer patients and their families to promoters of easy money-making schemes labeled in mysterious scientific dress, it is imperative that the standards of consumer protection set forth in the federal drug acts be maintained.

The Court of Appeals answered in the negative the question of whether there is a right of privacy inhering in the Constitution to choose medication for cancer that has not passed the premarketing clearance standards of the federal drug laws. The appeals court held that there was no such fundamental right and that the rational relationship tests applied to measure the ambit of the right claimed. The appeals court's decision followed on the heels of a decision by the highest court in California that held that the premarketing clearance requirements of the federal and state drug laws bear a reasonable relationship to the protection of public health by limiting a patient's choice of medications.[24] Petitioners claim that the compelling governmental interest test should apply and derides the lack of exhaustive case analysis by the appeals court. (See 616 F.2d 455 and Petitioners Brief, pp. 28-29) Exhaustive case analysis is not called for in here. The cases cited by the appeals

---

[24] People v. Privitera, 23 Cal. 3rd 697, 153 Cal. Reptr. 431, 591 P.2d 919 (1979), cert. denied, 444 U.S. 949 (1979).

court speak for themselves and support the standard of proof applied.[25]

Both the Federal Appeals Court and the Supreme Court of California rested their decisions on this Court's decisions in *Planned Parenthood of Missouri* v. *Danforth*, 428 U.S. 52 (1976); *Roe* v. *Wade*, 410 U.S. 113 (1973); and *Whalen* v. *Roe*, 429 U.S. 589 (1977).

Planned Parenthood of Missouri v. *Danforth* holds that choice among medical alternatives is not at this time a decision within the zone of constitutionally protected privacy. That decision stands for the proposition that although a decision of whether to have an abortion is within the constitutional zone of privacy, deserving the protection provided by the "compelling interest" standard, the selection of a particular abortion procedure is a medical matter to which privacy status does not attach and which may be regulated by government, provided a rational basis for such regulation exists.

In the instant case, the analogue of the right to decide whether to have an abortion is the right to decide whether to receive or forego cancer treatment. Although the decision whether to receive treatment may be constitutionally protected, the choice among treatment alternatives is not within the scope of the constitutional right to privacy. In *Planned Parenthood* the issue was whether the regulation reasonably relates to the preservation and protection of maternal health. Its analogue here is whether the rulemaking provisions of the federal drug laws reasonably relate to the preservation and pro-

---

[25] Whalen v. Roe, 429 U.S. 589 (1977); Planned Parenthood of Missouri v. Danforth, 428 U.S. 52 (1976); Paris Adult Theatre I v. Slaton, 413 U.S. 49 (1973); Roe v. Wade, 410 U.S. 113 (1973); Doe v. Bolton, 410 U.S. 179 (1973); and Eisenstadt v. Baird, 405 U.S. 438 (1972); see also People v. Privitera, 23 Cal. 3d 697, 153 Cal. Reptr. 431, 591 P.2d 919 (1979), U.S. cert. den., 444 U.S. 949 (1979).

tection of the health of the cancer patient. The highest court of the state of California and the federal appeals court correctly held that the state statute establishing a safety and efficacy standard reasonably relates to the preservation and protection of the health of cancer patients.

Roe v. *Wade* is significant in light of the constitutional issue raised, for it reflects this Court's recognition of the government's compelling interest in protecting individual health, and in protecting the public health generally where individual conduct may adversely affect the well-being of others. This court's decision in *Roe* holds that at some point during pregnancy the state's important interest in safeguarding health, in maintaining medical standards, and in protecting potential life became sufficiently compelling to sustain regulation of the factors that govern the abortion decision. The authority to protect individual health, and the public health generally, may be exercised to overrule the woman's personal decision to undergo a particular medical or surgical procedure during the second and third trimesters of pregnancy even when she is fully aware of the risks of the procedure, and is willing to take those risks.[26]

An individual's decision to use Laetrile can stand on no higher constitutional level than the decision of a woman to have an abortion in the later stages of pregnancy. The Commissioner's Laetrile Opinion makes clear the parallels between *Roe* and the case presented for review.[27] It was established in the Commissioner's Opinion on Laetrile that a significant number of cancer patients can be cured or have their lives extended by the use of effective therapy, especially when treatment is be-

---

[26] 410 U.S. at 162-165.

[27] E.g., the FDA rulemaking decision on laetrile, Laetrile, Commissioner's Decision, 42 Fed. Reg. 39768, 39782 (1977).

gun as soon as possible after diagnosis.[28] The availability of Laetrile serves to encourage delay among certain cancer patients in seeking effective therapy.[29] Moreover, even among patients who begin treatment of their cancers with effective therapy, the readily acknowledged side effects of that therapy may cause them to cease to use such methods at a time when their application still may be successful, and turn instead to Laetrile—"a painless cure." Because legitimate therapy may be stopped, delayed or avoided, many cancer patients will die needlessly or prematurely. This fact alone provides compelling justification for an even more stringent criteria than that relied upon by the federal appeals court and the California court for prohibiting interstate transportation and sale of drugs such as Laetrile absent compliance with the premarketing standards that are contained in federal drug laws and the California code.

Further, the appeals court's decision finds support in the rationale set forth by this Court in *Whalen* v. *Roe*, *supra*. There, the Court upheld a state statute requiring physicians to report the names and addresses of patients for whom the physicians had prescribed certain dangerous drugs to a state agency. The patients contended, among other things, that the statute invaded their constitutionally protected zone of privacy by depriving them of the right to decide independently, with the advice of a physician, to acquire and use needed medication. The Court upheld the statute, citing cases using ordinary, not "compelling interest" tests for the exercise of the police power and concluded that the impact of the statute on either the reputation or the independence of patients for whom the specified drugs are medically indicated is not sufficient to constitute an invasion of any right or liberty

---

[28] Id. at 39799.

[29] Id. at 39797, 39799.

protected by the Fourteenth Amendment. 429 U.S. at 603-604.

Finally, *Eisenstadt* v. *Baird*, *supra* note 25, supports the proposition that the premarketing clearance provisions are not in conflict with a right of privacy. This court held that unmarried individuals have a privacy right to purchase and use contraceptives, but noted that the contraceptives themselves, if they are new drugs within the meaning of the Federal Food, Drug and Cosmetic Act, would be subject to pre-market approval and the safety and efficacy standards. Laetrile has not passed that hurdle of pre-market approval.

Thus, the decision of the federal appeals court that there is no right of privacy to choose medications that have not passed the premarket clearance procedures of the federal drug laws is in accord with the decisions of this Court and does not provide an appropriate vehicle for certiorari.

CONCLUSION

The federal appeals court's interpretation of the federal drug laws on the grandfather and privacy issues is consistent with the opinions rendered in analogous cases by this Court. The decision by the federal appeals court is in keeping with the principles enunciated by this Court, and reinforces the protections provided by State and federal law for patients with life-threatening illness. For these reasons, Mr. Rutherford's petition should be denied.

Respectfully submitted,

GRACE POWERS MONACO
BARRY R. LENK
FAIRMAN, FRISK & MONACO
2025 Eye Street, N.W.
Suite 1022
Washington, D.C. 20006
202/296-3785

Attorneys for the
American Cancer Society, Inc.

September 19, 1980